Family Health International

Improving lives, knowledge, and understanding

Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) Program

WORKPLAN

August 2005 – June 2006

Cooperative Agreement No. GPO-A-00-05-00022-00

USAID FROM THE AMERICAN PEOPLE

Submitted on 21 September 2005 to:

U.S. Agency for International Development
Research Technologies Unit
1300 Pennsylvania Avenue, NW
Washington, DC 20523

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INTRODUCTION

BACKGROUND

The Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) Program is a five-year, $125 million cooperative agreement between USAID and Family Health International (FHI). This Agreement builds on more than three decades of FHI's experience and accomplishments in contraceptive technology and reproductive health research to advance and support USAID's family planning and reproductive health programs worldwide. The purpose of the cooperative agreement is to increase the range of available choices and the use of safe, effective, acceptable, and affordable contraceptive methods and reproductive health technologies, including microbicides, delivered through high-quality family planning and reproductive health services in developing countries. The CRTU Agreement was signed on April 29, 2005.

The intermediate results to be achieved through the Agreement are:

- Improved and new contraceptive and reproductive health technologies developed, evaluated and approved;
- Microbicides and microbicides/spermicides developed, evaluated and approved; and
- Use of contraceptives, microbicides and reproductive health technologies optimized and expanded.

In implementing the CRTU, FHI will give increased emphasis to working closely with service delivery partners, both other USAID cooperating agencies, as well as country-based agencies and NGOs to introduce technologies and scale up interventions that are shown through research to be successful in improving their use. FHI has signed MOUs with a number of these agencies to facilitate this 'research to practice' model. Collaboration with partners is also an important mechanism for setting the research agenda and priorities.

In keeping with the terms of the CRTU, FHI submitted a draft of the First Year Workplan on July 1, 2005, following a one and a half day retreat with senior CRTU and USAID technical and management staff. Written comments and questions for consideration were subsequently provided by USAID. These have been incorporated in expanding and finalizing this Year 1 Workplan, which represents the culmination of four months of collaboration with USAID, CA partners, and mission staff. Notably, planning for the next Workplan has already commenced in order to obtain the input of our MOU partners and others in the selection and design of future activities.

THE CRTU WORKPLAN PROCESS

Our process in developing this first Workplan was an iterative one involving numerous stakeholders. Multidisciplinary teams at FHI, in consultation with MOU partners, FHI field offices, and USAID, have developed five technical strategies that will guide the implementation of the CRTU:

- Barrier Methods (Male and Female)
- HIV/AIDS and Contraceptive Services
- Hormonal Methods
- Long Acting and Permanent Methods; and
- Microbicides

The technical strategies establish research and research utilization priorities, and set forth outcomes to be achieved by the end of the cooperative agreement. These priorities and outcomes will also serve as the basis for the CRTU monitoring and evaluation plan.
A sixth category of crosscutting activities will support the implementation of activities carried out under the technical strategies, facilitating the 'research to practice' agenda, including a focused effort to achieve impact in a few selected countries where the CRTU will concentrate resources for an "enhanced" program.

Staff from all FHI divisions implementing the CRTU, including field-based staff, were encouraged to submit concept proposals responding to the technical strategies and desired outcomes. Many of these concept proposals were also based on input from and discussions with MOU partners and others. Strategy working groups then reviewed and scored each of the concept proposals submitted under a particular strategy, using pre-established criteria, including the potential for public health impact, project design, and feasibility. All of the concept proposals, along with the strategy working group scores, comments and recommendations, were then reviewed by the CRTU Leadership Group, and final decisions were made regarding activities to be included in this first Workplan.

MAJOR THEMES IN THE FIRST YEAR WORKPLAN

This Workplan marks the beginning of a new Program and FHI's efforts to address the CRTU's goal and intended results. Some major themes are reflected in the proposed activities to be initiated this year.

HIV/AIDS and Contraceptive Services

First, the global impact of the HIV/AIDS pandemic has created a need for increased knowledge of the issues and challenges facing families as they plan the spacing of their children. Key research questions that are being targeted through the CRTU this year include:

- What are cost-effective models for integrating family planning services into HIV programs which will decrease unintended pregnancies to HIV infected women without decreasing condom use?

- How can research results be translated into scalable programs to increase contraceptive use among people at risk of HIV and people who are HIV infected, including women on ART?
- What are effective messages to increase pregnancy prevention and disease prevention among couples, youth, and men?
- Can a diaphragm be made available that is effective in preventing pregnancy and STI transmission but does not require a prescription or fitting?
- Can a new vaginal drug delivery system be developed that would provide protection against both pregnancy and STIs while also addressing some of the problems associated with the application of current vaginal methods?

With evidence-based responses to these key research questions, service delivery programs and policy makers can more effectively target their own efforts and better serve the needs of the communities in which they work.

Research to Practice and Enhanced Country Programs

Evidence shows that it takes approximately ten years for a new research result to be incorporated as standard public health practice. Obstacles include:

- There is no single "best" approach to ensuring research utilization, and the "best" approach for any specific situation may not be clear in advance.

- Large-scale program change requires substantial investment, and often the cost and time necessary to affect such change are underestimated. Inadequate financial and human resources may be significant limiting factors to success.

- Health professionals often suffer from information overload and are resistant to changing long-held beliefs and practices.

The CRTU Research to Practice efforts this year will address both international and country-specific objectives. From the global perspective, FHI staff will work with USAID to develop a best practices package to guide the work of collaborating agencies receiving USAID GH/PRH funding. Likewise, the staff will work within the IBP Consortium to share knowledge and build consensus among global partners on best practices principles within the RH arena. Within a few selected countries, FHI will work with identified public health leaders to form a "Network of Champions" which will both inform the research agenda and work to get research results incorporated into local and national programs.

We recognize one additional challenge facing researchers in the institution of best practices and methodologies:

- Fostering use of global-level research is more complex than use of locally derived research. Commitment to implement findings is likely to be greater when local stakeholders are involved in developing the research questions and interpreting the results.

We recognize the need to partner with service delivery organizations to ensure the implementation of a change process for improved public health. We will collaborate with global service delivery partners to develop feasible and responsive study designs that address issues of

relevance to partner agencies. We will also identify five *enhanced* countries in which targeted interventions will be modeled and refined for replication and scalability.

Optimizing and Increasing the Use of Existing Contraceptive Methods and Reproductive Health Technologies.

Subprojects in each of the method-related areas of CRTU investment, clearly strive to address IR3. In the absence of a thoroughly tested and approved microbicide, the focus in the Year One Workplan is on contraceptive methods and, to a lesser extent, on tools such as checklists which can aid providers in their practice. Some of this year's efforts which address increasing and optimizing the use of existing contraceptive methods include:

HIV and Contraceptive Services - Access to and knowledge about existing contraceptive methods is a cost efficient way of preventing unwanted pregnancies and averting HIV+ births. This program of work is best achieved through the integration of HIV and FP services.

Hormonal Methods - The "quick start" approach to combined oral contraceptive (COC) pill provision may be an effective means to prevent unwanted pregnancies by increasing accessibility and convenience to the client and decreasing the likelihood of misuse. In turn, continuous use of COCs may encourage continuation by reducing the symptoms associated with the 7-day hormone-free interval. Work on injectables will target efforts to expand provision through community health providers and evaluating a new tool for providers of injectables that encourages client continuation.

Long-Acting and Permanent Methods - Narrowing the knowledge gap of service providers and clinicians may encourage increased use of under-utilized contraceptive methods, like vasectomy and IUD. Research to practice efforts for Year 1 of the CRTU will target work in this key area. New research will include studying the introduction of the new implant Jadelle into Kenya and comparing its cost to donors, programs, and users with those for DMPA, oral contraceptives and IUDs.

Barriers –In addition to clinical trial work, FHI will conduct service delivery research including an evaluation of the "Young Men as Equal Partners" Project in both Uganda and Kenya. The cost-effectiveness of alternative female condom distribution systems will also be examined. FHI's Product Quality and Compliance Department's work is particularly notable in the area of barrier contraceptives where they continue to ensure the quality and reliability of USAID-procured condoms, participate in the review of international standards and test prototypes of new barrier contraceptives.

CRTU CORE BUDGET BREAKDOWN

FHI's guiding principles are: excellence, a "research to practice" approach, building capacity, focusing on the most pressing public health issues, and working in partnership with a wide range of cooperating agencies, international organizations and others to maximize the impact of our research and programs. Within this framework, FHI has created a program of work which allocates approximately 51% of the core budget to the achievement of research excellence in the five *contraceptive and reproductive health technology* strategic areas: HIV and Contraceptive

Services, Hormonal Methods, Long-acting and Permanent Methods, Barrier Methods and Microbicides. Some of the activities to be funded in these strategy areas represent pilot efforts to implement meaningful best practices generated from CTR research.

To facilitate new and further support existing partnerships to ensure program sustainability, capacity building and *research utilization*, FHI has allocated approximately 28% of its core budget in the areas of Research to Practice and Enhanced Country Program Implementation. At the forefront of all of our proposed research initiatives is the ultimate impact on public health issues. Other important initiatives receiving core funding reside in the areas of global leadership (11%), technical support (6%) and other program monitoring and evaluation efforts.

ORGANIZATION OF THE WORKPLAN

The document begins with a table highlighting our workplan budget by activity. This section is followed by a qualitative review which includes a brief description and workplan for each activity or subproject. The document is organized by technical strategies listed in the following order: HIV and Contraceptive Services, Hormonals, Long-acting and Permanent Methods, Barriers, Microbicides, Research to Practice (RtoP) and Information Programs, Technical Leadership and Other Cross-cutting. Within the strategies, activities have been sorted first by the goal they are seeking to address and, secondly, by the outcome(s) they are striving to impact or achieve. In this way, we can more easily track progress towards the defined CRTU outcomes.

In addition to these strategy areas, you will find budget figures for three technical support activities to receive core funding this year. They are: CONRAD Support, Information Resources Services (Library), and Regulatory Affairs and Quality Assurance. Formal descriptions and workplans for these activities are not provided as they represent key support functions. Each plays a supportive role for the other subprojects and allows for technical assistance to be provided upon request to the extent provided for by the funding level.

New activities are likely to be identified during the course of year and, as deemed appropriate through the same in-house review process explained above, these will be submitted for individual preliminary approval to USAID. This Workplan, however, details an ambitious first year program in moving us toward the goal advancing and supporting voluntary family planning and reproductive health programs worldwide.

FHI looks forward to working with USAID in its implementation.

CRTU Year 1 Workplan

Approved Activities List (Sept 2005 - June 2006)

Notes: 1) This budget represents available funds. Management costs have been subtracted from these activity totals. 2) Overall funds have been over-budgeted in anticipation of subproject cancellations, delays,

3) Outline indicates activities to receive funds from dual sources.

Group	Title	Fund Source	Workplan Available	Subproject Budget	LOSP Budget
HIV/AIDS and Contraceptive Services					
HSR	Developing Interventions to Serve the FP Needs of PMTCT Clients in SA	Core	x	150,000	358,000
FITS	Follow-up: Sharing Information on HIV and HC with Global Audiences	Core	x	191,300	191,300
CRD	Pharmacokinetic Interactions between DMPA and Selected ARTs	Core	x	110,000	295,812
FITS	Rapid Programmatic Assessment for FP-VCT Integration in Nigeria	Core	x	60,000	60,000
FITS	Tool Kit to Increase Access to Contraception	Core	x	187,261	250,000
HSR	Assessing and Meeting the Needs of Individuals in ART Programs	Core	x	169,278	335,925
		GLP		166,647	
FITS	Providing Global Leadership to FP-HIV Integration Efforts *(Technical Leadership activity)*	Core	x	100,000	300,000
		PEPFAR		75,000	
HSR	Improving Use of FP in VCT in Kenya	Core	x	191,098	415,118
		PEPFAR		52,900	
FITS	Kenya Information Management-HC and HIV/AIDS	FS	x	50,000	50,000
HSR/FITS	Increase PMTCT Program Effectiveness in Kenya	PEPFAR	x	236,000	236,000
FITS	PMTCT Performance Improvement in South Africa	PEPFAR	x	175,000	175,000
HSR	Risk of HIV and Feasibility Research Among House Girls in Nairobi	PEPFAR	x	182,000	182,000
FITS	Strengthening Linkages between FP, HBC and ARV Services	PEPFAR	x	365,000	365,000
Hormonals					
CRD	Continuous vs. Cyclic Use of COC Pills	Core	x	150,000	500,000
FITS	Contraceptive Discontinuation: Setting the CRTU Research Agenda	Core	x	124,550	124,550
CRD	Feasibility of Randomized Trial to Evaluate the Effect of DMPA on STI Risk	Core	x	150,000	150,000
HSR	Improving Continuation Rates for Injectable Contraceptives	Core	x	238,121	496,386
FITS	Pregnancy Provider Checklists and Reference Guide 2005	Core	x	50,000	125,000
FITS	Enhancing Access to Injectables through Community Health Providers	Core	x	138,720	250,000
CRD	RCT of QuickStart vs. Advance Provision of COCs	Core	x	40,480	40,480

Group	Title	Fund Source	Workplan Available	Subproject Budget	LOSP Budget
Long-Acting and Permanent Methods					
BASS/HSR	A Comparative Study of Vasectomy Accept. Among Clients and Providers	Core	x	257,373	438,772
CRD	Assessing the Future Role of Implants (PLACEHOLDER)	Core	x	100,000	220,000
FITS	Global Advocacy and Stakeholder Engagement for LAPMs	Core	x	100,000	200,000
FITS	Kenya IUD Revitalization-Transition Phase and M&E	Core	x	150,000	250,000
FITS	MAQ IUD Subcommittee and IUD Checklist Production and Dissemination	Core	x	125,000	235,000
FITS/HSR	OR-Male Motivators Promoting FP in the Nigeria Police Force	Core	x	90,000	250,500
HSR	OR-Staged Training of Private Sector Mid-wives to Increase IUD Use	Core	x	100,000	192,600
FITS	Repositioning FP-Revitalizing LAPMs in Uganda	Core	x	175,000	175,000
CRD	USAID Financial Support to Develop a Female NSS Method w/Erythromycin	Core	x	55,063	292,337
CRD	Vas Irrigation with Diltiazem	Core	x	31,000	31,000
Barriers					
CRD	Comparative Study-PATH's Soft-Cling WC and FC	Core	x	47,658	47,658
BASS/CRD	Developing Strategies to Recruit for True Efficacy Trials	Core	x	125,000	300,000
CRD	Evaluating Disinhibition in a Diaphragm Trial	Core	x	25,000	150,000
HSR	Evaluating the "Young Men as Equal Partners" Project	Core	x	200,000	492,000
FITS	Global Consultation on the Female Condom (SEE TECH LEADERSHIP)	Core	x	65,754	65,754
HSR	Measuring the Effectiveness of UNFPA-sponsored FC Promo Initiatives	Core	x	30,303	30,303
CRD	Next Steps for Clinical Reserch of New FCs	Core	x	200,000	350,000
CRD	Phase III Effectiveness Study of PATH SILCS Diaphragm	Core	x	269,871	1,092,437
CRD	Structural Integrity of the FC2 Female Condom	Core	x	35,000	35,000
FITS	ABC Approach for Youth on University Campuses in South Africa	PEPFAR	x	200,000	200,000
FITS	Testing the ABC Approach Among University Youth-Kenya	PEPFAR	x	240,000	240,000
PQC	Production Surveillance – Domestic Procurement - Condoms	CSL-FS	x	850,000	NA-Annual
PQC	Production Surveillance – Offshore Procurement - Condoms	CSL-FS	x	565,000	NA-Annual

Group	Title	Fund Source	Workplan Available	Subproject Budget	LOSP Budget
Microbicides					
CRD	Safety & Feasibility of the Diaphragm Used with Acidform	Core	x	198,852	198,852
BIOS	Carraguard Phase III Trial: Interim Analysis for DSMB, FCO #139100	Microb.	x	40,000	In Revision
BIOS/CRD	CONRAD: Phase II Study of Buffergel Duet, #9117, #2292	Microb.	x	25,000	In Revision
BASS	CS Phase III (for CONRAD), #9517	Microb.	x	1,000	In Revision
TBD	CS: HPV Prevention, #2298	Microb.	x	143,000	In Revision
CRD	CS: Phase IIII HIV trial, Nigeria, #2266	Microb.	x	2,723,000	In Revision
CRD	Develop Non-Woven Delivery System, FCO#2290	Microb.	x	25,000	In Revision
CRD	Independent Monitoring of CONRAD Collaborative Studies	Microb.	x	50,000	In Revision
BASS	Microbicides in India, acceptab, BASS (for HPTN), #9386	Microb.	x	270,000	In Revision
CRD	SAVVY: Phase III HIV study, #2277-2278	Microb.	x	4,923,000	In Revision
BIOS	Statistical support-microbicides, #9113, 139101	Microb.	x	10,000	In Revision
Cross-cutting: Research to Practice and Information Programs					
FITS	CRTU Knowledge Management	Core	x	535,000	NA-Annual
FITS	IBP Consortium	Core	x	20,000	20,000
FITS	Network of Champions	Core	x	81,000	255,000
FITS	Research to Practice Leadership	Core	x	289,000	1,250,000
FITS	USAID Best Practices Package: Development and M&E	Core	x	75,000	150,000
FITS	Evaluation of *What's New and Cool for Youth* Booklet	FS	x	170,000	170,000
FITS	Building Strategic Information Capacity within NASCOP in Kenya	PEPFAR	x	137,000	137,000
OIRE	Research Ethics Training Curriculum for Community Representatives	NIH	x	100,000	100,000

Group	Title	Fund Source	Workplan Available	Subproject Budget	LOSP Budget
Cross-cutting: Technical Leadership					
BASS	BASS Technical Leadership	Core	x	150,000	NA-Annual
BIOS	BIOS Technical Leadership	Core	x	150,000	NA-Annual
CRD	CRD Technical Leadership	Core	x	250,000	NA-Annual
CRD	Technical Leadership for WHO FP Guidelines	Core	x	124,220	213,047
CRD	Cochrane Fertility Review Group	Core	x	75,000	380,000
		NIH		75,000	
HSR	HSR Technical Leadership	Core	x	250,000	NA-Annual
PQC	Inter-Laboratory Trials	CSL-Core	x	40,000	NA-Annual
PQC	International Standards Development (ISO, ASTM, ANSI, etc.)	CSL-Core	x	20,000	NA-Annual
PQC	Technical Assistance to Field Programs	CSL-Core	x	215,000	NA-Annual
PQC	Technical Leadership: Collaboration with Multi/Bi-Lateral Procurement Agencies	CSL-Core	x	65,000	NA-Annual
PQC	Technical Oversight Committee	CSL-Core	x	60,000	NA-Annual
PQC	Test Capability Development and Enhancement	CSL-Core	x	100,000	NA-Annual
PQC	Production Surveillance – Domestic Procurement - IUDs, OCs, Injectables, etc.	CSL-FS	x	60,000	NA-Annual
PQC	Production Surveillance - International Procurement – IUDs, OCs, Injectables, etc.	CSL-FS	x	25,000	NA-Annual
Cross-cutting: Other					
EXO	CRTU End of Project and Project Launch Meeting	Core	x	100,000	100,000
FITS	Enhanced Country Program Implementation	Core	x	1,500,000	8,706,661
EXO	Monitoring and Evaluation of the CRTU Program	Core	x	250,000	1,350,000
FITS	Kenya DRHCD Follow-on	FS	x	195,199	212,500
Technical Support					
CRD	CONRAD Support	Core		250,000	250,000
EXO	Information Resources Services (Library)	Core		272,130	272,130
RAQA	Regulatory Affairs and Quality Assurance	Core		100,000	100,000

CRTU Year 1 Workplan
By Strategy

STRATEGY
HIV/AIDS and Contraceptive Services

Eleven of the 12 subprojects proposed under this strategy address the second goal which USAID indicated was its priority under the HIV/AIDS and Contraceptive Services strategy.

GOALS	OUTCOMES
I. To improve understanding of safety and effectiveness of contraceptive methods for women at high risk of HIV and HIV infected including women on ART	A. At least two clinical studies of the safety and effectiveness of hormonal contraceptives and ART completed. B. At least two studies, one study of a) hormonal contraception and one of b) IUD on the safety, effectiveness, and health benefits for women at high risk of HIV or HIV infected women completed, published.
II. To increase access, improve quality and expand use of contraceptives to safely prevent unintended pregnancies among people at high risk of HIV and HIV infected, including women on ART	A. At least three scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries. B. At least three strategies targeted to specific populations and implemented by HIV and/or FP providers developed, evaluated, and introduced into programs in five countries. C. Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births. D. International recommendations, country-specific guidelines, and program documents for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened. E. Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Pharmacokinetic Interactions Between DMPA and Antiretroviral Therapies

Status: To be approved

Projected End Date: April 30, 2006

Country(ies): Brazil

FCO:
2289
112108

Technical Monitor:
K Nanda
K Nanda

Subgrantee/Collaborating Agency: CEMICAMP [Center for Mother and Child Research of Campinas], Sao Paulo, Brazil

USAID Intermediate Objective to be addressed: IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: At least two clinical studies of the safety and effectiveness of hormonal contraceptives and ART [anti-retroviral therapies] completed.

Subproject Objective(s): 1) To evaluate the effect of common ARV therapies (AZT/3TC + EFV) on the pharmacokinetics of DMPA [Depo-Medroxyprogesterone Acetate]; and 2) to evaluate the effects of ARV treatment on bleeding patterns with DMPA.

Description: Pharmacokinetic data suggest that some antiretroviral (ARV) agents may affect the metabolism of single dose oral contraceptive steroids. But it is not clear whether these interactions actually result in a loss of contraceptive efficacy. No such data are available regarding the pharmacokinetics of DMPA and ARVs. This subproject will study the effects of selected ARV therapies on the pharmacokinetics of DMPA and on DMPA-related bleeding. Given the frequency of DMPA use for contraception among HIV-infected women, it is important to study potential drug interactions with ARV drugs, so that women being treated with ARVs can be properly advised about their contraceptive options.

This is a 12 week open-label, prospective non-comparative pharmacokinetic study of reproductive-aged women on current antiretroviral (ARV) therapy. Fifteen reproductive age HIV-positive women who have been receiving a standard regimen of ARV treatment for at least one month and who are willing to take a single dose of DMPA have been enrolled in this study. We have also enrolled 15 women on DMPA alone. Each woman will be followed for twelve weeks.

FY Workplan:

- Study follow-up will be completed in October 2005.
- Laboratory testing will be completed by November 2005.
- The close-out monitoring visit will be conducted in November 2005.
- Data analysis/manuscript writing will be completed by April 2005.
- Results of the study will be disseminated to programs.

Developing Interventions to Serve FP Needs of PMTCT Clients

Status: To be approved **Projected End Date:** October 31, 2007

Country(ies): South Africa

FCO: 114103 **Technical Monitor:** T Hoke

Subgrantee: TBD

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: At least three scalable and appropriate models--given the CPR, HIV prevalence, and available services--for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Subproject Objective(s): 1) To explore with providers and clients the feasibility and acceptability of alternative strategies for linking FP services to PMTCT services; and 2) to measure how such linkages affect FP uptake among women who have completed PMTCT services.

Description: South Africa's National Department of Health has given priority to providing Prevention of Maternal to Child Transmission (PMTCT) services to prevent HIV infections. Even though South Africa's national service delivery guidelines also advocate the provision of FP in the PMTCT package of care, few efforts have been made to integrate the two services. Failure to address the post-partum contraceptive needs of PMTCT clients, especially those known to be HIV-positive, is a grave missed opportunity, in the PMTCT service delivery system.

To address this issue, FHI proposes a two-phase study. **Phase 1** will consist of formative research to examine the feasibility of alternative strategies for serving the FP needs of PMTCT clients. Interviews with PMTCT clients in 15 sites will assess the priority they place on preventing or delaying a future pregnancy and will explore their interest in receiving FP services under different service delivery configurations. These would include during antenatal care, post-partum visits, infant feeding counseling sessions, and immunization and well baby check-ups. Providers and facility supervisors of each of these services will also be interviewed to assess their willingness to take on the added responsibility of providing FP services, and to determine how services would have to be modified to make this feasible. The appropriate level of integration—ranging from counseling and referrals to provision of the full range of methods—will also be explored from the clients' and providers' perspective. Results of data collection will be shared with program managers, who will identify one or two integration interventions that appear to be the most feasible.

Phase 2 will consist of operations research to test the selected interventions. It is anticipated that for each intervention, five matched pairs of PMTCT sites—or 10 in total—will be identified to participate. At baseline, PMTCT clients consenting to be re-contacted will be interviewed four months post-partum to assess their current contraceptive use. (Note: Sample sizes will be determined in consultation with Biostatistics during protocol preparation.) For each of the five matched pairs of PMTCT sites, one site will be randomly assigned to receive the intervention and the other site will continue delivering PMTCT as usual. After a 6-month follow-up period, another cross-section of PMTCT clients will be interviewed four months post-partum in the same manner as the baseline survey. The success of the intervention will be assessed by determining whether the proportion of former PMTCT clients using a modern contraceptive method increases more substantially (baseline to follow-up) among clients served by PMTCT sites with the FP intervention, compared to women served by traditional PMTCT services. Process data will also be collected to assess the extent to which the intervention was implemented as intended, and to gauge providers' and clients' satisfaction with the modifications to service delivery. Finally, the cost of

implementing the intervention—both the start-up costs and the cost of ongoing service delivery—will be computed to inform decisions about scale-up.

FHI plans to collaborate with a research group in South Africa that will contribute to several stages of the subproject: assisting with preparation of the protocol, particularly concerning research site information; assisting with ethical and technical clearances in South Africa; recruiting and training field workers and managing data collection; and assisting with report preparation and organization of meetings with stakeholders.

FY Workplan:

- The protocol will be completed, with technical and ethical reviews and approvals obtained.
- Subagreement established with a research group in South Africa.
- Interviews with clients and providers will be completed (Phase 1 formative research).
- Phase 1 interview data will be analyzed.
- Report on formative research will be prepared, along with a Power Point presentation.
- A meeting will be held with PMTCT program managers in South Africa to identify one or two FP-PMTCT integration interventions to be tested in Phase 2.

Strengthening Linkages between FP, HBC and ARV Services

Old Title: Increasing Access to ARVs and Essential Reproductive Health Services by Clients Receiving Home-Based Care

Status: To be approved **Projected End Date:** September 30, 2006

Country: South Africa

FCO: 153105 **Technical Monitor:** E Canoutas

Subgrantee: Project Support Association – South Africa (PSA-SA), South African Council of Churches (SACC)

Collaborating Agency(s): Right To Care, BroadReach, SACC, and PSA-SA

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: At least three scalable and appropriate models (given the CPR, HIV prevalence, and available services for integrating family planning and HIV services) designed, evaluated, and introduced in up to five countries.

Subproject Objective(s): 1) To build communication and referral skills of home based care (HBC) volunteers regarding pregnancy prevention as an effective PMTCT approach; 2) to build clinical counseling skills of family planning (FP) providers and ARV providers regarding pregnancy prevention as an effective PMTCT approach, and contraceptive methods that are safe for HIV-infected women and HIV-infected women on ARVs; 3) to build the skills of HBC volunteers to provide basic information about the availability of and access to ARV services, and to assist HBC clients to adhere to the treatment regimen; and 4) to conduct a process evaluation of the subproject.

Description: Since 2003, FHI has supported the Project Support Association – South Africa (PSA-SA) HIV/AIDS home-based care (HBC) program to integrate FP into the basic package of services provided by volunteers in Mpumalanga province. Access to FP services is a key public health intervention, particularly in the context of HIV. Simulation models suggest that HIV prevention goals can better be met when a combination of interventions are used, including access to contraception for HIV-infected women in PMTCT programs. It is anticipated that improved access to ARV services in South Africa will lead to improved health status of many HIV-positive individuals, leading to a return of libido and sexual activity, and thus requiring new decisions about contraception. Tighter linkages between care, ARV and contraceptive services will be needed so that women not only have the opportunity to improve their quality of life, but also to make informed decisions about their fertility.

With funding from the President's Emergency Plan for AIDS Relief, this subproject will create functional referral mechanisms between HBC, FP and ARV service programs in Mpumalanga and Kwazulu-Natal provinces to increase access to FP as well as ARV services, and to meet in a holistic fashion, the health care and treatment needs of HBC caregivers, clients and their families.

FHI will collaborate with two organizations supporting local HBC programs – PSA-SA and SACC – to implement the program in 30 HBC project sites. FHI will be responsible for the work related to creating referral mechanisms and providing FP technical assistance. Right To Care and BroadReach will be responsible for working with the volunteers on HIV counseling and testing and ARV adherence monitoring, respectively. Staff from FHI's Institute of HIV/AIDS will be involved in the oversight of ARV and VCT activities.

The overall subproject activities will include HBC project site identification, training needs assessment, curricula design/review, intervention implementation, monitoring and supervision, documentation of lessons learned through a process evaluation, and reporting on PEPFAR targets.

FY Workplan:
Staff will:

- Work with PSA-SA and SACC to identify 30 HBC project sites and determine training needs.
- Design training, TA materials and provider tools.
- Build and strengthen referral networks between 40 DOH FP clinics, 20 DOH and NGO ARV providers, and 30 PSA-SA and SACC HBC projects in Mpumalanga and Kwazulu-Natal provinces.
- Provide TA to 300 HBC volunteers to identify FP needs among over 40,000 clients, caregivers and their families and to refer them to FP clinics.
- Conduct two trainings for 40 FP and 20 ARV providers on appropriate contraception for HIV-infected women of childbearing age and HIV-infected women on ARVs (using FHI FP/ARV module).
- Train 300 HBC volunteers to assist clients to begin using and monitor adherence to ARV therapy (in collaboration with BroadReach and FHI Institute for HIV/AIDS staff).
- Partner with Right To Care to provide counseling and testing in the HBC setting (in collaboration with FHI Institute for HIV/AIDS staff).
- Support PSA-SA's and SACC's overall HBC programs by building reporting and supervision skills through two trainings and ongoing TA.
- Conduct a process evaluation of the program to determine effectiveness and potential for replication.
- Report on the President's Emergency Plan targets and indicators.

Improving Use of FP in VCT

Status: To be approved

Projected End Date: December 31, 2006

Country: Kenya

FCO:
Core 153103
2nd FC0, TBD, PEPFAR

Technical Monitors:
H Reynolds
R Wilcher

Collaborating Agency: Kenya MOH

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: At least three scalable and appropriate models (given the CPR, HIV prevalence, and available services for integrating family planning and HIV services) designed, evaluated and introduced in up to five countries.

Subproject Objective(s): 1) To determine the effect of family planning provision in VCT on the uptake of contraceptive methods among VCT clients; 2) to develop and target messages to men in VCT programs and assess whether these efforts strengthen family planning messages and services for men; and 3) to determine how to strengthen overall VCT providers' family planning messages and provision for both men and women.

Description: Despite international support and modeling evidence, no confirmation of the effectiveness of integrated family planning/HIV services exists. Specifically, we lack an understanding of whether integrated services result in contraceptive uptake, continuation, and prevention of unintended pregnancies and HIV positive births. This subproject, which will be co-funded with CRTU core funds and funds from the President's Emergency Plan for AIDS Relief, seeks to strengthen the provision of integrated FP-VCT services in a subset of VCT centers in Kenya and evaluate the effect of integrated services on contraceptive uptake.

CRTU core funds will be used to conduct research activities, collect formative data with male VCT clients and conduct activities to inform strengthening of family planning provision in VCT centers. The effectiveness of efforts to improve the use of family planning services in VCT will be measured by assessing the proportion of VCT clients at risk for unintended pregnancy who begin using a method of contraception. We will rely on a two-group, post-test-only design. We will collect data from a subset of clinics receiving strengthened integration activities and from a group of control clinics. Monitoring data from the modified client card will be needed to complement OR results.

Formative research will be conducted with male VCT clients to understand what messages they want and need regarding family planning. Information obtained from formative research will be synthesized into supplemental material that can be appended to the existing FP-VCT training and IEC materials. We will rely on data collection activities described above to evaluate the added contribution of efforts to strengthen family planning messages and services for men.

The development and implementation of the enhanced integration intervention will be funded by PEPFAR. While the specific intervention activities will be informed by the formative research and findings from a previous CTR operations research study on FP/VCT integration in Kenya (FCO 9390), core components of the intervention will likely include additional training with VCT providers and strengthened supervision for trained providers. All of these activities will be implemented in collaboration with the MOH in Kenya.

This subproject will allow FHI to provide global technical leadership in the area of FP-VCT integration by increasing understanding of how to strengthen VCT providers' provision of family planning messages and services for both men and women. By determining the effect of an enhanced integration intervention on contraceptive uptake, this subproject will provide useful information for other countries and for Kenya to expand and include contraceptive services in VCT.

FY Workplan:
Staff will:

- Develop and get protocol approved;
- Obtain appropriate ethical approvals;
- Implement M&E activities with revised client card and obtain buy-in from facility and district stakeholders;
- Conduct formative research with male VCT clients;
- Develop activities to strengthen male-targeted messages in VCT;
- Use information from OR results (FCO 9390) and conduct formative research to understand how to strengthen the VCT-FP integration intervention;
- Develop enhanced training and supervision activities;
- Train VCT providers in FP-VCT integration;
- Provide support to MOH for facilitative supervision activities; and
- Develop and get approval for OR data collection instruments.

Risk of HIV/AIDS and Feasibility of Research among House Girls in Nairobi

Status: To be approved **Projected End Date:** 06/30/06

Country(ies): Kenya

FCO: 154100 **Technical Monitor:** S Thomsen

Subgrantee: Kenyatta University

USAID Intermediate Objective to be addressed: IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: At least three strategies targeted to specific populations and implemented by HIV and/or FP providers developed, evaluated, and introduced into programs in five countries.

Subproject Objective(s): The goal of the assessment is to provide more information on the risk level of female domestic workers (house girls) for contracting HIV/AIDS in order to inform a potential intervention. To this end, the assessment will: 1) map knowledge of HIV/AIDS, sexual experiences, behaviors and sexual networks of house girls; 2) determine the feasibility of conducting an intervention study with house girls and/or their sexual partners; 3) use the information gathered to develop an appropriate intervention to be implemented in a follow-up study with the same population; and 4) develop a protocol for an add-on intervention study, if one is deemed feasible.

Description: House girls work as maids in modest or higher income households in Kenya. According to the Republic of Kenya/UNICEF (1994), 84% of the house girls in Kenya have no formal education or had dropped out of school before completing the primary cycle. They are young: 98% of the house girls in Nairobi are below the age of 18. House girls earn 1-4 USD a week, and work between 9-18 hours a day. Some are orphans; some experience sexual exploitation.

A recent study of HIV/AIDS information of 120 house girls in Nairobi (Wainaina, unpublished) found that they were sorely lacking in knowledge about HIV/AIDS transmission and management. For example, 74% thought that one can tell a HIV carrier by the way they look. Although 72% said they had heard about voluntary counseling and testing (VCT), only 45% of these knew what the functions of VCT are and only 2% had sought the services of a VCT center. Only 2% knew about the relationship between STIs and HIV/AIDS. Two-fifths (44%) did not know what unprotected sex is, while 42% did not believe that a condom protects one against HIV/AIDS.

Because of their vulnerable situation and lack of knowledge, house girls in Kenya are in a potentially high-risk position. However, little research has been done on house girls and there are still many unknown factors concerning their level of risk. For example, it is not known to what degree house girls in Kenya are sexually active or with whom they are having sex. Further, the nature of these relationships is unknown. It could be that their sexual relationships are of a non-consensual nature, which means that they will have little say in reducing their risk. Finally, there is uncertainty about what kind of intervention would be most helpful to house girls, and how it would work, given that they are allowed little freedom of movement outside their place of work and may be hesitant to be interviewed.

This assessment will employ two primary methods to elicit the information needed to develop an appropriate intervention and study design: 1) formative, in-depth interviews with house girls to elicit information on knowledge of HIV/AIDS, risky sexual behavior and experience with non-consensual sex and/or violence, to map sexual networks, and to determine the feasibility of their participation in a cohort study; and 2) key informant interviews with members of the community (such as church leaders,

community HIV/AIDS educators) and employers of the house girls to develop a feasible strategy to conduct an intervention and study.

If such an intervention appears feasible, the information gained from this formative assessment will lead to the development of an intervention, which will have as its goal the reduction of risky sex among house girls. Kenyatta University will oversee the day-to-day implementation of data collection and the development of any intervention.

FY Workplan:

- A protocol and sub-agreement will be approved.
- Six data collectors will be trained.
- Fifteen in-depth interviews with house girls and 7-10 interviews with key stakeholders will be carried out.
- Data will be analyzed.
- An internal report will be written.
- A meeting of stakeholders will be held in Nairobi in January or February 2006.
- An intervention strategy and training manual will be developed.
- A protocol for an add-on study will be developed if appropriate.

Assessing and Meeting FP Needs of Individuals in ART Programs

Status: To be approved **Projected End Date:** September 30, 2007

Country(ies): Ghana

FCO: TBD **Technical Monitor:** S Adamchak

Collaborating Agency(s): FHI/Institute for HIV/AIDS; EngenderHealth

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births

Subproject Objectives: 1) To document process and output indicators of the intervention to integrate FP in ART services; 2) to assess the effect of the intervention on contraceptive use and fertility intentions over time; and 3) to assess the impact of the intervention on the number of pregnancies reported per month over a 12-month time period.

Description: While contraceptive services should be an integral component of comprehensive HIV care, this is often not the case. As is the case with all women, HIV+ women need to be able to choose the number and timing of their pregnancies. HIV+ woman also need to be informed about any potential harmful effects of ART drugs on the developing fetus. Contraception may avert HIV+ births by preventing unintended pregnancies. Research has found poor infant outcomes and increased risk of maternal mortality and morbidity among HIV-infected women, compared to those uninfected.

Little is known about how the availability of ART affects fertility desires of women and men living with HIV/AIDS. It has been hypothesized that as health status improves with ART, some individuals may resume or increase sexual activity and wish to have children, while others may not want to become pregnant. Documenting changes in fertility intentions and monitoring pregnancy status over time among individuals receiving ART can inform HIV programs about appropriate strategies for incorporating family planning into their services.

This work will be a joint undertaking among FHI's IMPACT Program, which supports four ART sites in Ghana, EngenderHealth's ACQUIRE Project, which plans to train providers to offer FP counseling and services at these sites, and the FITS and HSR Divisions of FHI, which will evaluate the implementation of the intervention and its effects.

Relevant process and output indicators will be measured including: whether accurate and appropriate FP information is communicated by providers; provider attitudes and willingness to provide FP services; contraceptive uptake; referrals made; and the impact of providing FP on other services included in the ART program. Data collection methods will include observation of client-provider interactions, provider interviews, client exit interviews, and activity sampling. To assess changes in contraceptive use, fertility intentions, and pregnancy status among clients, a prospective cohort study design will be used, comparing a cohort of clients exposed to the intervention activities to a cohort of unexposed clients. Data collection methods will include client interviews, anonymous pregnancy tests, and medical record reviews.

FY Workplan:
- Staff will develop monitoring and evaluation data collection tools

- Enrollment of women in the sample will be conducted to monitor changes in contraceptive use, fertility intentions, pregnancy status (number TBD based on final research design and patient load at project sites).

Providing Global Leadership on FP and HIV Integration

Status: To be approved **Projected End Date:** June 30, 2008

Country(ies): Worldwide

FCO: 113104 **Technical Monitor:** R Wilcher

Subgrantee:

Collaborating Agency(s): Numerous, TBD

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
- International organizations responsible for setting guidelines and informing policy reviews to change or strengthen international recommendations, country-specific guidelines, and program documents for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened.
- Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Subproject Objectives: 1) To strengthen support for family planning as an HIV prevention intervention; 2) to promote dissemination and utilization of the latest scientific evidence and programming tools on FP/HIV integration and contraception for HIV-infected and at-risk women; 3) to establish partnerships and collaborations with other organizations working on HIV and contraception activities; and 4) to facilitate strategic placement of new HIV and contraception research and programs in the field.

Description: For the past two years, FHI has become increasingly involved not only in research and programs designed to increase contraceptive use in the context of the HIV/AIDS epidemic, but also in leadership efforts to garner support for such research and programming. By establishing and coordinating USAID's Family Planning and HIV/AIDS Integration Working Group, hosting key events at international HIV/AIDS and RH conferences, and facilitating country-level integration efforts, FHI has been at the forefront of efforts to expand access to and use of contraceptives by HIV-infected and at-risk women.

This subproject will support a number of activities that will allow FHI to build on the leadership role it has established in the arena of HIV and contraception and continue to advance research and programming.

First, FHI will continue to participate in and provide leadership to the Family Planning and HIV/AIDS Integration Working Group.

Second, FHI will host satellite sessions on HIV and contraception-related topics at high-profile international HIV/AIDS and/or RH conferences.

Third, FHI will maintain involvement in and operation of field-based working groups addressing HIV and contraception issues.

Finally, FHI will leverage and work with its Research-to-Practice Network of Champions to foster local partnerships and collaborations on integration activities and identify field-based opportunities to apply emerging research findings.

All of these activities will contribute to: increased awareness of the importance of contraception as an HIV prevention intervention; improved dissemination and utilization of the latest scientific evidence on

FP/HIV integration programming and contraception for HIV-infected and at-risk women; and the strategic placement of more integration research and programming in the field.

FY Workplan:

- Staff will organize and host a special session on HIV and contraception at the 2005 Reproductive Health Priorities conference in South Africa at which the latest scientific evidence on the relationship between hormonal contraceptive use and HIV risks will be presented.
- Staff will participate in the November 2005 meeting of the Family Planning and HIV/AIDS Integration Working Group.
- Staff will identify advocates from HIV/AIDS organizations, such as the International Community of Women Living with HIV/AIDS, to participate in the 2005 meeting of the Working Group.
- Staff will coordinate the participation of HIV/AIDS advocates in the Working Group meeting.
- At the Working Group meeting, participants develop workplans within the research, service delivery, and advocacy small groups that contain actionable items for advancing FP/HIV integration efforts between the semi-annual meetings of the Working Group.
- Staff will provide technical support to the small groups to ensure follow-through on action items prior to the spring 2006 meeting of the Working Group.
- In collaboration with Enhanced Country Program efforts, staff will develop a scope of work for research utilization champions that focuses on advocating, identifying field-based opportunities, and enhancing partnerships for integration programming and research.
- Staff will convene at least two meetings with field-based working groups and partners addressing HIV and contraception programming and research issues.
- Staff will initiate the planning process for hosting a satellite session at the XVI International AIDS Conference in Toronto in August 2006.
- Staff will participate in the spring 2006 meeting of the Family Planning and HIV/AIDS Integration Working Group.

Tool Kit to Increase Access to Appropriate and Effective Contraception for HIV+ Clients

Status: To be approved **Projected End Date:** December 31, 2006

Country(ies): Worldwide

FCO: 113106 **Technical Monitor:** I Yacobson

Collaborating Agency(s):
EngenderHealth; Center for Communication Programs (Johns Hopkins Bloomberg School of Public Health).

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
- Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs
- International recommendations, country-specific guidelines, and program documents for contraceptive use by people at risk of HIV and HIV-infected, including women on ART, changed or strengthened.

Subproject Objectives: 1) To synthesize information on current practices and interventions being used in integrated programs to address the RH/FP needs women and couples with HIV; and 2) To develop a Tool Kit that will include a tailored training package and other tools to guide FP/HIV integration activities.

Description: Increased access to antiretroviral (ARV) therapy and the resulting improvements in health are giving many clients with HIV a renewed optimism about the future. Thus, demand for contraception among clients with HIV, especially those on ARV therapy, is expected to increase. Use of effective contraception reduces the risk of pregnancy, giving women with HIV easier access to a wider range of ARV drugs. Contraception can also play a major role in prevention of mother-to-child transmission (PMTCT) of HIV by preventing unintended pregnancy.

While the evidence on "best practices" for integration of HIV and FP services is limited, it is important to offer initial guidance to programs and providers to move integration efforts forward. In order to do that, information on current practices and interventions will be collected through literature reviews and direct communication with staff in country programs implemented by FHI and possibly other partners. Additionally, rapid assessments of provider and client needs, as well as challenges in integrated programs, will be conducted in several countries with ongoing FP/HIV integration activities.

This information will be used to develop a Tool Kit that will include, and adapt for worldwide audience, FHI's module *Contraception for Women and Couples with HIV,* developed in collaboration with EngenderHealth with support from USAID/REDSO/ESA. It will also include training materials tailored to providers with different technical backgrounds, needs assessment tools, facility readiness checklists, job aids for providers, and others. EngenderHealth and the Center for Communication Programs will contribute to the development of additional resources.

The training materials will then be field-tested in at least two countries among HIV/AIDS care and treatment providers and FP providers. Following the field-testing and expert review of the Tool Kit, a final package will be produced and distributed in digital/CD-ROM format.

FY Workplan:

- Staff will meet with stakeholders/partners during Reproductive Health Priorities Conference in South Africa in October 2005 to identify needs and possible tools for inclusion.
- Staff will conduct a literature review of current practices and interventions in the field of FP/HIV integration.
- Staff will establish contacts with programs in countries conducting integration activities and collect information on their experiences through interviews.
- Staff will conduct at least three rapid assessments of provider and client needs as well as challenges in integrated programs (e.g., West Africa, East/Southern Africa, Asia).
- Staff will compile the findings from the data collection activities to create an outline of the Tool Kit and circulate it to stakeholders for comments and input.
- Staff will develop a draft of the Tool Kit that incorporates stakeholder suggestions.
- Staff will pre-test portions of the Tool Kit as appropriate.
- Staff will adapt the existing module, *Contraception for Women and Couples with HIV* for use by a worldwide audience.

Sharing Information on HIV and Hormonal Contraception (Follow up)

Status: In-approved **Projected End Date:** June 30, 2006

Country(ies): Worldwide

FCO: 113119 **Technical Monitor:** K Best

Collaborating Agencies: To collaborate with the World Health Organization, the U.S. National Institutes of Health, and the Gates Foundation in organizing and holding an Africa regional meeting on hormonal contraception and HIV acquisition to be held in Nairobi, Kenya, on September 19-21, 2005.

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome to be addressed: International recommendations, country-specific guidelines, and program documents for contraceptive use by people at risk of HIV and HIV-infected, including women on ART, changed or strengthened.

Subproject Objectives: 1) To give policymakers, program managers, providers, and women in high HIV prevalence countries, as well as other countries, information necessary for informed decision-making about hormonal contraception; 2) to increase trust and confidence in hormonal contraceptive use, in particular, and family planning programs, in general; and 3) to bolster activities to reposition family planning in the era of HIV/AIDS.

Description: Data from a soon-to-be published FHI-led study funded by NICHD will help clarify the relationship between hormonal contraceptive use and HIV acquisition and answer questions about the safety of hormonal contraceptive use by family planning clients. This subproject continues a global, multi-partner information dissemination campaign, the planning of which was undertaken in the first half of 2005. The present subproject seeks to disseminate this emerging research to ensure that appropriate family planning counseling messages are conveyed.

FY Workplan:

- Partial support will be provided to WHO-sponsored Africa regional meeting, to be held in Nairobi, Kenya, in September 2005. The meeting will bring together approximately 100 researchers, policymakers, program managers, and women's advocates working in the HIV and reproductive health fields to learn about the relevant scientific data and discuss the possible programmatic and policy implications. The Gates Foundation and the National Institutes of Health are providing the majority of financial support for this meeting; monies from this subproject supplement and leverage that support. They will help finance FHI's key role in: 1) facilitating the meeting's organization; 2) leading a communication strategy session to prepare meeting participants to accurately present to key audiences information about hormonal contraceptive use and HIV upon return to their respective countries; and 3) writing up the meeting's proceedings.
- Upon publication of the FHI-led study (anticipated during fiscal year 2005-2006), electronic dissemination – to more than 75,000 health decision-makers, opinion leaders, providers, and health media – of various FHI-produced background materials. Dissemination of these materials in English, Spanish, and French will reach FHI and USAID contacts, and will then be further enhanced through reprint agreements and re-broadcasting by Web sites, listservs, and commercial online services.
- Publication of an issue of *Network* dedicated to the topic of hormonal contraceptive use and HIV acquisition, transmission, and disease progression. Writing and editing for the issue were largely completed under the CTR. However, given unanticipated delays in publishing the FHI-led study, final review, translation into French and Spanish, printing, and distribution of this final *Network* issue were put on hold and now fall under the CRTU. Standard distribution to some 45,000 readers will be

expanded to meet requests by FHI publications subscribers for an additional 3,000 copies in English, French, and Spanish.

- A pre- and post-meeting survey at the Africa regional meeting to determine how the meeting affected participants' knowledge and attitudes about the safety of hormonal contraceptive use in regard to HIV acquisition, and to identify persistent knowledge gaps or misperceptions.
- Following these dissemination activities, monitoring of media coverage of the topic and changes in providers' knowledge, attitudes, and practices. If there is any indication of continuing misunderstandings about the relationship between hormonal contraceptive use and HIV acquisition, further information dissemination activities may be called for.

Information Management on Hormonal Contraception and HIV-AIDS

Status: To be approved

Projected End Date: June 30, 2006

Country(ies): Kenya

FCO: TBD

Technical Monitor: J Kimani

Subgrantee: N/A

Collaborating Agency(s): Ministry of Health, Kenya Medical Association (KMA), Kenya Obstetrics and Gynaecologist Society (KOGS), National Nurses Association of Kenya (NNAK), University of Nairobi, Medical Training Institutions, JHPIEGO, EngenderHealth, Population Council and Kenyatta National Hospital

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Subproject Objective(s): To disseminate country-specific, evidence-based information on the relationship between hormonal contraceptive use and HIV risks to Kenyan stakeholders in the Ministry of Health, family planning and HIV/AIDS organizations, professional associations, training institutions, nongovernmental organizations and the media.

Description: Until recently, data on the possible relationships between hormonal contraceptive use and risk of HIV acquisition, transmission, and disease progression have been conflicting and inconclusive. However, data from a soon-to-be published FHI-led study sheds more light on these important interactions. Given the heavy reliance of Kenyan women on hormonal methods, a country-specific dissemination strategy is needed to minimize misinterpretation of study results about the relationship between hormonal contraceptive use and HIV acquisition. Efforts are also needed to sensitize service providers on recommended contraception choices for HIV-infected women and couples. This subproject will disseminate accurate information on the role of effective contraception in HIV programs to stakeholders in the Ministry of Health, family planning and HIV/AIDS organizations, professional associations, training institutions, nongovernmental organizations and the media.

The dissemination effort will be composed of four main activities:

First, FHI will collaborate with the family planning working group of the Ministry of Health's Division of Reproductive Health (DRH) and other key policy makers and program managers to customize the background materials on the research study results to Kenyan audiences.

Second, FHI staff members, in partnership with the DRH, Kenya Obstetrics and Gynecologist Society (KOGS), and Kenya Medical Association (KMA) and JHPIEGO, will plan and facilitate half-day professional development meetings for members of training institutions and nongovernmental organizations and family planning service providers in selected provincial/district capitals in Kenya.

Third, FHI will monitor and respond to media inquiries, and/or misinformation in Kenya and will work closely with several key health reporters to provide background on the FHI-led study, inform them of the results and key messages and promote balanced reporting.

Finally, FHI staff members will document the information management process.

FHI assistance for this subproject was requested by the Kenyan MOH and USAID/Kenya has provided funding to support its implementation. This subproject targets a CRTU enhanced country and leverages knowledge management products on this topic being developed under a complementary subproject.

FY Workplan:
FHI staff will:

- Convene meetings with the DRH working group and other key stakeholders to discuss study results, review informational materials on the study, and discuss how to customize materials for a Kenyan audience.
- Tailor materials to Kenyan audiences.
- Solicit feedback from the working group on tailored materials and revise as needed.
- Print and disseminate materials through strategic information-sharing channels.
- Develop plans for professional development meetings.
- Organize and facilitate seven professional development meetings.
- Prepare materials for the media to facilitate accurate communication of study findings.
- Provide ongoing documentation of the information dissemination/management process.

PMTCT Performance Improvement in South Africa

Status: To be approved **Projected End Date:** September 30, 2006

Country(ies): South Africa

FCO: TBD **Technical Monitor:** W Castro

USAID Intermediate Objective to be addressed: IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Subproject Objective(s): To provide technical assistance to 30 sites in South Africa to design, develop, and implement high quality, comprehensive and cost effective PMTCT programs, with an emphasis on strengthening family planning counseling and referral.

Description: Taking a case study approach in FY04, Family Health International (under the CTR) in partnership with the South Africa National Department of Health (NDOH) investigated the factors contributing to successful PMTCT services. A program was defined as successful if it had an uptake of each PMTCT component in excess of 80% of eligible clients. The assessment also explored the feasibility of linking family planning services to PMTCT services that currently focus primarily on antiretroviral prophylaxis. Evaluation findings were shared with PMTCT program managers, who can apply the lessons learned as they scale up PMTCT services and ensure the quality of existing sites.

During FY05, with funding from the President's Emergency Plan for AIDS Relief, FHI will use the information generated from FHI's previous investigation of high performing sites to design, develop and implement high quality, comprehensive and cost-effective PMTCT programs in 30 PMTCT sites. Using core funds from the CRTU, FHI will continue to provide TA under the new subproject to a selection of the 20 sites that received TA under the South Africa Country Operational Plan (COP) 04 funding cycle. These sites are located in Limpopo and Northern Cape provinces. FHI also will provide TA to additional PMTCT sites in these provinces for a total of 30 sites combined.

The TA provided under this funding cycle will build upon the lessons learned from the assessment by identifying the factors that contribute to the success of high performing PMTCT sites. These best practices will be adapted for and transferred to programs in the 30 selected sites.

Evidence from the assessment indicates that family planning is an underdeveloped or neglected component of most PMTCT packages. Hence, the TA will focus on strengthening the family planning counseling and referral component of PMTCT services. Approximately 10 providers per site (a total of 300 providers) will be trained to meet these goals. The information gathered from the performance improvement investigation will also be used to inform a review of national PMTCT program policies and guidelines and provincial protocols in South Africa.

FY Workplan:

- FHI will collaborate with provincial managers in selecting districts and sites. A total of 30 sites in two provinces will be chosen. A selection of the 20 sites that received TA under the COP 04 program will be carried forward and continue to receive TA under this subproject.
- Based upon lessons learned from the FHI/NDOH investigation and from the COP 04 PMTCT TA program, FHI will design and offer technical assistance in areas that include, but are not limited to: awareness and demand creation; protocol development; pre- and post-test counseling skills; family planning counseling and referrals; and supervision. A total of 300 nurses, lay counselors, doctors,

supervisors, and program managers/administrators will receive training to strengthen their skills in technical areas listed above.

- FHI will collect process evaluation data and prepare a report based on the process data.

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Increasing PMTCT Program Effectiveness

Status: To be approved

Projected End Date: August 31, 2006

Country: Kenya

FCO: 154101

Technical Monitor: H Reynolds

Collaborating Agency: Kenya MOH

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded.

Strategy Outcomes to be addressed: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Subproject Objective(s): 1) To identify 20 high performing sites and 60 "typical" PMTCT sites with stakeholders; 2) to determine what elements appear to increase the proportion of HIV+ pregnant women obtaining ARV prophylaxis, delivering in facilities, participating in infant feeding counseling and receiving postpartum family planning methods; and 3) to implement best practices identified during the assessment (objective #2) in 60 PMTCT sites.

Description: PMTCT services in Kenya are characterized by many missed opportunities to extend services to women and their newborns who need them. A recent assessment conducted at a provincial hospital in Mombasa found that fewer than one quarter of the women who tested positive for HIV were able to complete all steps in the existing PMTCT program. One option to improve uptake of nevirapine is to reach women during delivery. But only 40% of women deliver under the care of skilled providers. Moreover, these providers are not typically engaged in HIV testing and nevirapine provision. Another missed opportunity is postnatal feeding counseling and family planning services. Breastfeeding alone accounts for an estimated 15-20% of mother-to-child transmission of HIV. To ensure that HIV infected women practice appropriate infant feeding methods, suitable messages must be reinforced during the postnatal period. However, current PMTCT programs do not follow women after they give birth. Also important, and usually overlooked during the postnatal period, is to focus on the prevention of unintended or mistimed pregnancies among HIV infected women.

The subproject has two components. The **first** is an evaluation of high performing sites to determine what elements appear to increase the proportion of HIV+ pregnant women obtaining ARV prophylaxis, delivering in facilities, participating in infant feeding counseling and receiving postpartum family planning methods. The **second** component will implement identified best practices in non-high performing sites to improve uptake of PMTCT services in Kenya. This subproject will take place in nine districts (Nairobi, Kilifi, Mombasa, Makueni, Machakos, Naivasha, Kajiado, Buisa and Kakamega) making up five provinces (Nairobi, Coast, Easter, Rift Valley and Western).

FY Workplan:
- Develop and seek approval for protocol and data collection instruments.
- Secure approval from appropriate ethical committees.
- Coordinate activities with the MOH's PMTCT Technical Working Group.
- Identify criteria for "high performing" sites.
- Identify 20 high performing sites and 60 "typical PMTCT sites with stakeholders.
- Evaluate best practices in 20 sites.
- Work with partners to identify "known" best practices.
- Conduct interviews with PMTCT providers and managers and conduct observations of client-provider interactions.

- Construct observations using a structured data collection form and conduct activity sampling in a subset of high performing sites with diverse HIV prevalence levels.
- Use results to scale up the quality of PMTCT services in 60 sites by working with PMTCT implementing partners.
- Monitor key indicators in scale up sites.

Rapid Programmatic Assessment for FP-VCT Integration

Old Title – Piloting a Replication of the Kenya Model for FP-HIV Integration in Nigeria

Status: To be approved **Projected End Date:** June 30, 2006

Country(ies): Nigeria

FCO: 113105 **Technical Monitor:** W Castro

Subgrantee: N/A

Collaborating Agencies: Nigerian Ministry of Health; GHAIN [Global HIV/AIDS Initiative Nigeria]

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Subproject Objective(s): To generate and document strategic information on potential facilitating factors and obstacles to integrate family planning and VCT services effectively in the Nigerian context.

Description: Nigeria meets the definition of a generalized HIV epidemic. Accordingly, USAID's technical guidance on FP/HIV integration recommends that all FP and HIV services should be integrated. Currently, as part of the GHAIN [Global HIV/AIDS Initiative Nigeria] program, FHI is working with the uniformed services in Nigeria, focusing on integrating FP/RH and HIV services. USAID/Nigeria is committed to integrating SO13 (FP/RH, Child Survival, and Basic Education) and SO14 (HIV/AIDS and TB) interventions for the general population as well.

This subproject supports rapid programmatic assessment for FP/VCT integration as the first phase in a holistic approach to integrating FP and VCT services, which will directly contribute to USAID/Nigeria's integration goal. As the key agency coordinating the integration activities with the uniformed services, we are recognized by USAID/Nigeria and other implementing partners as a leading group working to move forward integrated FP and HIV services in Nigeria and have recently received additional funding from USAID/Nigeria to support integration.

Choosing VCT programs as the entry point for integrating FP provides increased access to family planning information and services for many clients, particularly men and youth, who are sexually active and of reproductive age and who normally do not access family planning services. Nigerian national guidelines for VCT were revised in 2003 with technical assistance from FHI. Current VCT guidelines include the integration of FP into VCT programs. Yet the provision of VCT services in FP programs has not been instituted to meet the new guidelines. The information gathered through the rapid programmatic assessment will assist the MOH in closing the gap between Nigeria's integrated VCT guidelines and actual service provision. As the process moves forward, integrating FP into VCT programs in the Nigerian context will provide us with a unique opportunity to build upon lessons learned from other countries as well as test models of integration in settings with different epidemiological profiles, thus adding critical information to the evidence base of integration.

Specifically, under this subproject, FHI will conduct a rapid programmatic assessment to gather information needed to gain support and answer key questions that will influence the design and implementation of future FP and VCT integrated programming efforts. The assessment will be carried out

in a select number of GHAIN focus states to gauge VCT sites' preparedness for integrating FP, and to explore opportunities and obstacles to integrating FP into VCT services.

The assessment will gather information through key informant interviews to assess: 1) current demand for FP at VCT service sites and the extent to which referrals are being provided; 2) acceptability among key stakeholders, including attitudes of policy makers, program managers, providers, and clients toward integrating family planning into VCT services: perceived advantages and disadvantages; and 3) opportunities and challenges to integrating family planning into VCT services, including current training, logistics and facility capacity, and options for strengthening linkages and referral networks between family planning and VCT services. Stakeholder involvement in interpreting the results of the assessment is crucial to obtaining buy-in and support for the development of the integrated programming. Results from the programmatic assessment will be shared with the stakeholder group to guide the development of an appropriate program intervention.

FY Workplan:

- FHI will convene a stakeholder meeting with representatives from the Nigerian MOH (NASCOP and DCDPA), COMPASS, GHAIN and ENHANSE to elicit support and input for the rapid programmatic assessment process.
- FHI will collaborate with GHAIN staff and the MOH to identify VCT centers and key informants to be interviewed. Sites will be chosen within the different tiers of health facilities (government owned, tertiary, secondary and non-governmental sites) to provide information on the feasibility of integrating FP and VCT in different settings.
- Drawing on FHI's experience in Kenya and Ghana, FHI will develop/adapt assessment methodology and data collection tools.
- FHI will hire consultants who, with guidance from the FHI Technical Monitor and the Senior Reproductive Health Advisor to GHAIN, will carry out key activities for the rapid programmatic assessment.
- In an initial planning phase, consultants will conduct a desk review, collecting policy and programmatic guidelines for family planning and VCT service provision in Nigeria and information on the distribution of FP and VCT services throughout the country.
- Consultants, with guidance from FHI, MOH, and other key stakeholders, will conduct a rapid programmatic assessment through key informant interviews at the selected sites to gather information on program preparedness for integrating services.
- Consultants will analyze the content of the interviews and synthesize the findings into a draft report.
- Consultants will work with FHI to prepare a final report of the desk review and rapid assessment findings that will be disseminated to stakeholders.
- FHI will disseminate the final report from the programmatic assessment to the stakeholder group to further inform the development of an appropriate program intervention for integrating FP and VCT services.

STRATEGY
Hormonal Methods

The goal designated in bold below is the one which USAID has indicated as their priority in the area of hormonal contraception. Six of the seven subprojects proposed in this workplan address that goal. The seventh subproject addresses the last goal.

GOALS	OUTCOMES
I. To bring to market new hormonal and non-hormonal reversible contraceptives.	A. A more efficient design than the traditional long-term follow-up study for studying the efficacy of methods developed, evaluated and shared with other research organizations, funding agencies, and other interested parties. B. In collaboration with partners, a new, reversible, short term female contraceptive submitted to the FDA, other regulatory bodies, or other interested parties as appropriate. C. In collaboration with partners, a new reversible short term male contraceptive submitted to the FDA, other regulatory bodies, or other interested parties as appropriate.
II. To improve uptake, continuation rates and use patterns of existing hormonal contraceptives	A. Self-injection of injectables such as subcutaneous DMPA introduced in at least one country. B. Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated. C. Strategies to enhance uptake of hormonal methods developed and evaluated. D. Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated. E. Policies and service delivery guidelines will be changed in at least one country to reflect new research findings.
III. To expand the use of newer hormone delivery systems such as rings and patches in developing countries.	A. The impact of newer delivery systems on continuation, compliance, and pregnancy rates in developing countries assessed. B. If feasible and cost competitive, newer delivery systems introduced in at least one country.
IV. To establish the relative benefits of the currently available short-term hormonal methods.	A. A job aid to assist programs, providers and clients in assessing and balancing competing risks of using different hormonal and non-hormonal methods tested in at least one country. B. Results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and other interested parties for incorporation into practice and procurement decisions.
V. To answer important questions about positive and negative non-contraceptive effects of currently available hormonal methods	A. Critical questions regarding the long term safety and benefit of hormonal contraceptives identified, and at least one high priority question addressed through research. B. Results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and other interested parties for incorporation into practice and procurement decisions.

Pregnancy Checklist and Provider Reference Guide 2005 Update & Implementation

Old title: Pregnancy Provider Checklist and Reference Guide 2005 Update & Implementation

Status: To be approved **Projected End Date:** June 30, 2008

Country(ies): Worldwide

FCO: TBD **Technical Monitor:** C Lasway

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded.

Strategy Outcomes(s) to be addressed: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated.

Subproject Objective(s): 1) To update the FHI Pregnancy Checklist in accordance with WHO's 2004 Medical Eligibility Criteria; 2) To revise pregnancy checklist reference materials and to produce and disseminate 2,000 reference guides and 9,000 pregnancy checklists; and 3) To promote the pregnancy checklist to CAs and PVOs, and provide technical assistance for its implementation and use in at least three in-country programs, in an effort to reduce medical barriers and increase access to FP.

Description: In many countries, 25 to 50 percent of women are denied a contraceptive method on their first visit to a family planning clinic because they are not menstruating at the time. The FHI checklist "How to be reasonably sure a client is not pregnant" provides an easy-to-use screening tool for various levels of health care providers, including physicians in resource-poor settings, pharmacists, or staff stationed at health posts. FHI research in Kenya and Guatemala demonstrated that the pregnancy checklist virtually eradicated the practice of turning away non-menstruating clients. The pregnancy checklist was developed based on WHO Medical Eligibility Criteria and under the CTR, it was both passively and actively disseminated through mailing lists, *Network*, conferences/workshops, and focused efforts under Research to Practice. It is a simple, low-cost job aid, easily implemented and replicable by in-country program managers with little or no assistance from FHI. FHI has not evaluated wider dissemination and use, but believes further outreach to CAs would encourage greater use in USAID-funded programs. Under the CRTU, FHI will work to promote the checklist to pharmacies, VCT clinics, and other non-traditional family planning outlets, to increase access, improve referral mechanisms, and ultimately impact public health.

This subproject will provide support for technical review/update, printing, and dissemination of the Pregnancy Checklist, as well as the development of appropriate background materials in the form of a reference guide to facilitate implementation by programs. A Pregnancy Checklist promotion strategy will also be developed, outlining focused dissemination/outreach efforts including global and enhanced focus-country components. It will include a systematic approach for documenting dissemination, follow-up, and (where possible) use of the checklist over a three-year period.

Workplan:
- Staff will conduct a technical review/update of the Pregnancy checklist in English, French, Spanish, and Kiswahili.
- Graphic design layout and print production of 5,000 copies of the Pregnancy checklist in English, and 2,000 each in French and Spanish will be completed.
- Staff will update, print, and disseminate 2,000 informational packages/reference guides to accompany the Pregnancy Checklist.
- Staff will development of a dissemination strategy and mechanism for follow up and M&E of uptake.
- Staff will collaboration with at least one MoU partner or other CA/PVO to implement the checklist in a country-based program.

RCT of Quick Start vs. Advance Provision of COCs: Bleeding and Continuation

Status: Ongoing

Projected End Date: December 31, 2006

Country(ies): Nicaragua

FCO:	Technical Monitor:
112109	KNanda
1383	KNanda
1351	KNanda
2274	KNanda

Collaborating Agency(s): Profamilia, Managua

USAID Intermediate Objective to be addressed: IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:

- Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.
- Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated.

Subproject Objective(s): 1) To determine if the 'quick start' approach leads to higher continuation rates than advance provision of COCs over the 6 month duration of the study; 2) to determine if bleeding patterns for those subjects given COCs immediately (Quick Start) are not worse than in those subjects given COCs to start at their next menses onset (Advance Provision).

Description: It is estimated that over 1 million unintended pregnancies are related to OC use, misuse or discontinuation. Most current recommendations advise that women should start COCs at the beginning of a menstrual cycle (within the first 5-7 days). In the USA, women presenting beyond the beginning of their cycle are commonly given a pack of COCs and told to start at the beginning of their next cycle. Some women given this advice may not start the pills due to misunderstanding or other intervening events, such as pregnancy. In developing countries, women who are not menstruating are often sent home without any COCs and told to return at the time of next menses.

Innovative approaches to COC initiation could increase uptake, improve continuation, and ultimately decrease pregnancy rates among women wanting to use these contraceptives. In this prospective, randomized controlled clinical trial conducted at a family planning clinic in Managua, 230 healthy women with regular menstrual cycles, who request combination oral contraceptives and are not in the first 7 days of their menstrual cycles were randomized to COCs given by either Advance Provision (N = 115) or the Quick Start approach (N = 115). The primary endpoint was continuation through 6 months, and secondary endpoints included: continuation through 3 months, menstrual bleeding patterns, test characteristics of the pregnancy checklist among potential participants, and 6-month pregnancy probabilities. This study was initiated under the CTR. Enrollment for this study was completed in January, 2005, and follow-up was completed by June 2005. Additional time, supported through the CRTU, will allow completion of data analysis, paper-writing, and dissemination of findings.

FY Workplan:

- FHI staff will complete data analysis.
- FHI staff will draft and submit a manuscript for publication.
- FHI staff will work with Profamilia to disseminate relevant results in the field.
- As appropriate, results will be incorporated into the RtoP initiative.

Continuous Versus Cyclic Use of Combined Oral Contraceptive Pills: Continuation, Acceptability, and Side Effects

Status: To be approved

Projected End Date: August 31, 2007

Country(ies): TBD

FCO: TBD

Technical Monitor: K Nanda

Collaborating Agency(s): TBD

USAID Intermediate Objective to be addressed: IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Subproject Objective(s): To evaluate continuation rates, adherence, and acceptability of combined oral contraceptives (COCs) used by the 21/7 cyclic regimen compared with continuous use.

Description: Over 1 million unintended pregnancies are related to OC use, misuse or discontinuation. COC discontinuation rates are very high in developing countries, ranging from 16% in Zimbabwe to 52% and 73% in the Dominican Republic and Turkmenistan, respectively. The monthly regimen of 21 active pills followed by 7 inactive pills was created to mimic spontaneous menstrual cycles. However, the 7-day hormone-free interval is associated with withdrawal symptoms including bleeding, pain, breast tenderness, bloating/swelling and headaches. Alternate regimens of oral contraceptive pills, in which the duration of the active pill phase is longer than 21 days and/or the placebo phase is shorter than 7 days, may provide advantages over currently available standard 28-day regimens by reducing symptoms associated with the hormone-free interval, decreasing bleeding (and potentially anemia), enhancing acceptability, and thus improving continuation rates. There are no published data on the use or acceptability of extended use COC regimens in women in developing countries.

This will be a prospective, randomized, controlled clinical trial, to be conducted in a family planning clinic in a developing country. Approximately 300 healthy 18-40 year-old, nonpregnant, and nonlactating women with regular menstrual cycles will be randomized to monophasic COCs (ethinyl estradiol 30 mcg and levonorgestrel 150 mcg) using either the conventional 21/7 regimen or continuous use. Participants in the continuous COC group will use pills continuously unless bleeding or prolonged spotting signals need for a hormone-free interval. We will evaluate pill continuation through 6 months, assess adherence, acceptability (both quantitatively and qualitatively), bleeding, and side effects. Additional outcomes are pill instruction comprehension, 6-month pregnancy probabilities, and hemoglobin levels.

FY Workplan:

- The study team will be selected and initial planning meetings will be held.
- FHI staff will draft a protocol, and submit it to PHSC for approval.
- FHI staff will draft data collection forms and develop qualitative data collection methods.
- FHI staff will conduct site evaluation visits, negotiate budgets, and select a site.
- The study will be initiated at the selected site.

Contraceptive Discontinuation: Setting the CTRU Research Agenda

Old Title: Extending Contraceptive Protection

Status: In-approved **Projected End Date:** June 30, 2006

Country(ies): U.S.

FCO: 113102 **Technical Monitor:** E McGinn

Collaborating Agencies: TBD

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome to be addressed: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Subproject Objectives: 1) To convene a research agenda-setting workshop, in collaboration with FHI service delivery MOU partners and experts from enhanced countries, to develop a joint plan for research to reduce discontinuation of hormonal methods; and 2) To develop knowledge management materials to support workshop discussions and to promote the agenda agreed to at the workshop.

Description: Worldwide, over 100 million women use hormonal contraception, and this use is increasing. However, hormonal contraceptive prevalence may be a misleading measure of the success of family planning programs. Research suggests that at least 30 - 40 percent of women in many developing countries discontinue hormonal methods during the first year of use. Greater understanding and sharing of successful interventions to reduce discontinuation is needed to develop programmatic best practices.

FY Workplan:

- A workshop will be held in the U.S. to review evidence on the best interventions to improve hormonal contraceptive continuation. This meeting, modeled after such successful efforts as the Vasectomy Experts Meeting (December 2003) and the IUD CA meetings (July and November 2003), will bring together key individuals from the CA/private voluntary organization community to review evidence (including that synthesized in the document described below) and share recent programmatic experience. Meeting participants will be charged with identifying knowledge gaps and setting research and research-to-practice priorities. The meeting will also serve as an opportunity for CA/MoU partners to work collaboratively and to influence FHI research protocols related to improving contraceptive continuation.
- A synthesis document will be prepared about hormonal method discontinuation as background to inform the workshop discussions. This 10- to 20-page paper will draw heavily on published articles and literature reviews, summarizing major questions/issues about hormonal method discontinuation. It will:
    - i Describe factors associated with discontinuation.
    - ii Examine the relationship between service quality and discontinuation.
    - iii Address potential complications in interpreting data about discontinuation.
- Workshop proceedings will be written and distributed..

Improving Continuation Rates for Injectable Contraceptives

Status: To be approved **Projected End Date:** January 1, 2008

Country(ies): South Africa and TBD

FCO: 114102 **Technical Monitor:** JN Baumgartner

Subgrantee: TBD

Collaborating Agency(s): TBD

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Subproject Objective(s): The overall study goal is to improve continuation rates for injectables contraceptives. More specifically, it is to develop and test an intervention tool for family planning providers that will: 1) reduce the proportion of DMPA/NET-EN clients who discontinue (i.e. do not come back at all); 2) reduce the proportion of DMPA/NET-EN clients who are late for their re-injections; and 3) increase the proportion of late DMPA/NET-EN clients who leave the clinic with a re-injection or another temporary contraceptive method until their next scheduled re-injection.

Description: Injectable contraceptives such as DMPA and NET-EN increasingly account for a larger proportion of the modern contraceptive method mix for women in low-resource settings, however, continuation rates for injectable contraceptives are low globally. In addition to women who choose to discontinue, a proportion of women who are considered “discontinuers” by providers and researchers, are in fact, women who are actually late for their re-injections but want to continue using injectables, as evidenced by a recent FHI study in South Africa. The proposed study will address improving continuation rates for injectables by focusing on both those clients who purposefully choose to discontinue as well as late clients who intend to continue but may be mismanaged by providers when they return for re-injections.

This is a prospective cohort study of hormonal injectable users to be conducted in two countries (South Africa and TBD). The study will develop and evaluate a new tool for providers that encourages client continuation (by having clients who are well-informed about the injectable method including the possibility of menstrual disturbances) and helps ensure re-injections for late clients who would like to continue using injectables. The intervention will be composed of: 1) enhanced counseling by providers for initial injectable clients; and 2) provider training on how to manage late continuing injectable clients. Enhanced counseling at the initial acceptor session will emphasize menstrual disturbances, the primary reason for discontinuing injectables, other side effects, when to return for re-injection, and condom use (dual protection) for HIV prevention. These messages will be on the intervention tool that the provider can easily utilize in a short counseling session. Provider training on management of late DMPA/NET-EN clients will also utilize the intervention tool (i.e. checklist and/or flowchart design) for gauging how "late" a client is (based on local grace period definition and what to do if client is 1, 2, or more weeks late for re-injection), how to rule out pregnancy if tests are not available, and determining whether to provide the re-injection or another method on the same day the client arrives for services.

For each study country, a representative sample of family planning clinics will be randomized (intervention vs. control group) and new injectable clients (# TBD) will be followed up for six to nine months. The intervention will be training of providers on the developed tool (pre-tested with providers in each study country and based on WHO recommendations) for initial counseling messages and

management of late continuing clients. Continuation rates for initial users will be calculated and the proportion of clients who are late for their follow-up re-injections will be estimated in addition to whether they receive a contraceptive method in the intervention versus control clinics. We anticipate working with service collaborating agencies as we collaborate on plans for provider training and utilization of the developed tool.

FY Workplan:

- A study protocol will be developed and USAID and PHSC approval obtained.
- Study countries will be finalized and local implementing agencies will be identified in 2 countries. The Women's Health Research Unit at the University of Cape Town in South Africa will likely be the first collaborating agency.
- Identify service delivery partners interested in results and future scale up of intervention.
- Site visits and subagreements will be negotiated in each study country.
- An intervention will be developed and pre-tested with family planning providers in each country
- An intervention will be revised and finalized.
- There will be training of research staff on the study protocol.
- Intervention and data collection will begin.

Expanding Access to Injectables Through Community Health Providers

Status: To be approved **Projected End Date:** September 30, 2007

Country(ies): Uganda and either Tanzania OR Kenya

FCO: TBD **Technical Monitor:** K Kruegar

Collaborating Agency(s): Save the Children; either EngenderHealth/Tanzania OR GTZ/ Kenya (partner agency and site will be determined once subproject and funding levels have been formally approved)

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
This subproject aims to address the following three outcomes of the hormonal methods strategy:

- Strategies to enhance uptake of hormonal methods developed;
- Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and;
- Policies and service delivery guidelines will be changed in at least one country to reflect new research findings.

Subproject Objective(s): 1) To improve the quality of family planning services offered at selected community health programs in Uganda and one other East African country by providing technical assistance for the expansion of contraceptive options to include injectable contraception; 2) to generate interest in scale-up and replication of Depo Provera provision by community health workers among policy-makers and community health programs throughout the African continent and other regions; 3) to initiate discussions with Ministries of Health in Uganda and one other East African country, which may result in amendment of National RH Guidelines so that eligibility to provide injections is based upon appropriate training and demonstrated skill; 4) to update FHI's DMPA Checklist in line with the WHO Medical Eligibility Criteria and disseminate it; and 5) to produce and print 500 toolkits or "how-to" guides to enable programs to expand their choice of contraceptive methods to include injectables (revised checklist will be included).

Description: The results of a recent cohort study conducted by FHI in collaboration with Save the Children USA (FCO 9327) demonstrate the safety, feasibility, and acceptability of community-based distribution (CBD) of DMPA in a rural Ugandan district. The study results reinforce the wealth of successful experiences from other regions such as Asia and South America, and provide a strong basis to affirm that well trained community health workers can provide injectable contraception safely in the African context.

Given the reproductive health challenges in the proposed East African countries, improvements in access to and knowledge of contraceptive options, can have a tremendous impact on the reproductive health outcomes of women. In addition, since DMPA is a strongly preferred method in the proposed country sites (accounts for over 40 percent of the method mix) and since community health programs remain an important mechanism for contraceptive distribution in the rural areas, the introduction of injectables to this distribution system has the potential to increase demand for DMPA, and substantially increase contraceptive prevalence.

This subproject will involve a multi-tiered approach. First, FHI will strengthen our efforts in Uganda to build consensus, expand provision of DMPA by community health workers, and amend national family planning guidelines. Second, a toolkit will be designed to enable community health programs to expand their choice of contraceptive methods to include injectables. Third, FHI will develop and implement a

comprehensive action plan in collaboration with a selected partner in East Africa to implement Depo Provera service provision in their community health programs. Finally, FHI will disseminate and showcase the toolkit as a means to generate interest and further promote inclusion of DMPA among methods provided by community health workers throughout the African continent and other regions.

FY Workplan:

Uganda

- Develop an action plan in collaboration with Save the Children and the Ministry of Health to expand provision of DMPA by community health workers in the Luwero and Wakiso districts of Uganda.
- Provide technical assistance to Save the Children for the training and deployment of community health workers, as well as documentation of challenges and lessons learned.
- Develop and implement an advocacy plan in collaboration with the Ministry of Health to build consensus among existing community health programs for implementation of changes in practice regarding provision of DMPA by community health workers.
- Initiate discussions with and provide technical assistance to the Ministry of Health in Uganda for the amendment of national family planning guidelines so that eligibility to provide injections is based upon appropriate training and demonstrated skill, not upon job title.

TBD Country, either Tanzania or Kenya

- Develop a collaborative action plan with the Ministry of Health and a selected partner to promote provision of DMPA by community health workers in at least one district (plan will include strategies for advocacy, training, procurement of commodities, consensus-building, and adaptation/development of resource materials).
- Provide technical assistance for implementation of the action plan, including training and deployment of community health workers.
- Document challenges and lessons learned from project implementation.

DMPA Checklist

- Conduct technical review of the existing DMPA checklist.
- Revise, re-design, produce, and print 2,000 DMPA checklists.

Toolkit

- Develop an advanced draft of the implementation toolkit.
- Develop a distribution list for the toolkit.
- Identify forums where the toolkit can be showcased (i.e. regional conferences).

Feasibility of a Randomized Trial to Evaluate the Effect of DMPA on STI Risk

Status: To be approved **Projected End Date:** June 30, 2006

Country(ies): Worldwide (several countries)

FCO: TBD **Technical Monitor:** E. Raymond

Subgrantee: TBD

Collaborating Agency(s): TBD

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved

Strategy Outcomes(s) to be addressed: Critical questions regarding the long term safety and benefit of hormonal contraceptives identified, and at least one high priority question addressed through research.

Subproject Objective(s): To determine whether or not the proposed randomized trial is feasible, and if so, to develop a plan for implementing it.

Description: Data from several recent observational studies have suggested that use of progestin-only contraceptive methods may increase the risk of acquisition of sexually transmitted infections (STIs), including chlamydia (CT), gonorrhea (GC), and HIV. However, this conclusion is suspect because of possible failure to control adequately for selection bias and confounding. For example, a higher rate of risky behaviors among progestin-only method users than among non-users could result in an apparent but false association between method use and infection. Considering the public health importance of both progestin-only methods and STIs, clarification of this issue is urgently needed. In addition, the role of herpes simplex virus (HSV) infection in mediating an increased HIV risk associated with depot medroxyprogesterone acetate (DMPA), as suggested in one recent study, needs further evaluation. The best way to provide this clarification would be through a randomized trial. This subproject will support activities aimed at assessing the feasibility of a randomized trial to investigate the effects of DMPA on the incidence of GC and CT and possibly HSV, and if feasible, support the application to other donors for funding to implement the trial.

These activities will include:

- developing the trial protocol;
- selecting appropriate study sites: This activity will require surveys at multiple locations to assess the feasibility of recruitment and the incidence of GC/CT/HSV in prospective trial populations, and visits to sites that seem promising; and
- investigating sources of funding for the trial.

FY Workplan:

- At least one potential site will be identified.
- Staff will develop survey tools for determining the feasibility of recruitment and STI incidence at the sites.
- At least one site visit will be made and feasibility surveys planned.

STRATEGY
Long-Acting and Permanent Methods

Of the nine subprojects proposed under the long-acting and permanent method strategy, six address the first goal noted above, one addresses the second goal, and two address the third goal. The goal of expending IUD use is addressed but the outcomes associated with those efforts relate to the more general LAPM goals.

GOALS	OUTCOMES
A. To promote feasible, evidence-based models for revitalizing under-used LAPMs and/or introducing new LAPMs.	A. At least three effective and replicable approaches for increasing demand for LAPMs identified. B. At least three programmatic approaches to improve service provider performance and client access to LAPMs identified and tested. C. Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.
B. To develop a safe, effective, and acceptable method of non-surgical female sterilization ready for introduction into FP programs within ten years.	A. An FDA-regulated Phase II clinical trial of a nonsurgical female sterilization method will be underway and negotiations with a private sector licensee will be initiated.
C. To increase male acceptance, support for, and uptake of LAPMs (including vasectomy).	A. Evidence provided from two or more demonstration projects (in partnership with service-delivery organizations) on effective approaches to increasing male involvement in FP and uptake of vasectomy. These might include evaluation of new techniques (such as low-cost thermal cautery equipment) in low-resource settings or demand-creation activities. B. At least one spermicidal agent that could prove effective in hastening azoospermia after vasectomy evaluated. C. The effectiveness of more easily reversible methods of vasectomy, such as the Shepherd IVD (intra-vas device), and their impact on method uptake evaluated.
D. To substantially expand IUD use by decreasing medical and other access barriers, as well as increasing demand and contraceptive choice.	A. New IUDs and IUS evaluated for effectiveness, uptake, continuation rates, and side effects, with emphasis on special populations such as nulliparous women, and introduced in at least three countries.

Assessing the Future Role of Implants

Status: To be approved

Projected End Date: June 30, 2007

Country(s): Kenya

FCO: TBD

Technical Monitor: D Hubacher

Subgrantee: TBD

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: At least three effective and replicable approaches for increasing demand for LAPMs identified.

Subproject Objective(s): 1) To evaluate the Kenyan experience with implants; 2) to compare Jadelle with DMPA, oral contraceptives and IUDs in terms of costs to donors, programs, and users; and 3) to provide donors with information necessary to determine whether they should begin purchasing implants for their programs.

Description: Kenya was the Population Council's regional training center for Norplant introduction in the 1980s and has led the African continent in implant technology ever since. Although Norplant is being phased out, Jadelle (the new two-rod product) has recently arrived. Last year, the Kenyan Ministry of Health received a German bank donation of 20,000 sets of Jadelle and began providing the method in select facilities in November 2004. The supplies were exhausted within 6 months, even in sites such as the Kenyatta National Hospital, where the government was charging $5.33 for the implants compared to only $0.67 for a three-month supply of oral contraceptives or a DMPA injection. Apparently, the high initial cost did not deter women from choosing Jadelle, even in this public-sector setting. After seeing this enthusiastic demand for Jadelle, the Kenyan MOH quickly arranged a second donation of 45,000 sets, which are due to arrive soon. The recent enthusiasm for Jadelle and implants in general provides an important opportunity to review this country's experience with implants and evaluate the potential role this method may play in the long-term in family planning programs across the region.

Though Jadelle provides contraceptive protection for up to 5 years, from a donor's perspective, it may be too expensive for purchase relative to other reversible forms of contraception. For the amount of money it would cost to buy 100,000 sets of Jadelle, a donor could purchase enough DMPA to protect approximately 160,000 women from pregnancy for 5 years or enough oral contraceptives to protect 400,000 women. However, if Jadelle has high satisfaction rates and most women use it for 5 years before removal, the method may prevent more unintended pregnancies than common alternatives, and thereby be relatively cost-effective. If comparisons are made to the copper IUD, a donor could buy 3.2 million devices with the amount of money that would be spent on Jadelle.

The key purpose of this subproject is to gather information that will help donors determine whether Jadelle is a worthwhile investment. We will conduct primary data collection to estimate the method continuation rate of Jadelle and interview women who have recently chosen Jadelle (to understand why they chose the method, long-term use intentions and method substitution issues). For comparative purposes, we will collect similar information on DMPA/OC, and possibly IUD, users. In addition, we will assemble the following information from secondary sources: the cost to donors of the methods, the costs to health systems to provide the methods to users, the costs to users of maintaining contraceptive protection. In this cost analysis, we will also include the copper IUD and the methods we use will follow the lead of previous research on Norplant introduction in Thailand (see Janowitz, et al., 1994). In

addition, we will conduct focus group interviews with Kenyan clinicians who have past and current implant experience to assess their view of how Jadelle complements the provision of standard family planning methods. Together, the information generated from this subproject will help donors decide whether to add Jadelle to their programs, and if so, whether the purchase should affect the quantities of other donated commodities.

FY Workplan:

- Staff will conduct a historical review of implants in Kenya.
- Staff will develop a detailed plan for conducting primary data collection, with input from multiple divisions at FHI.
- Staff will begin assembling the necessary data.

A Comparative Study of Vasectomy Acceptability among Clients and Providers in Two Districts

(Note: This subproject is a merger between two former concept proposals - *A Comparative Study of Vasectomy Acceptability in Two Districts of Uttar Pradesh, India* and *Development of a Rapid Assessment Tool to Revitalize Vasectomy Provision*)

Status: To be approved

Projected End Date: June 30, 2007

Country(ies): India

FCO: 116100

Technical Monitor: G Guest

Subgrantee: TBD

Collaborating Agency(s): ICMR (India), PSP-One, and (possibly) EngenderHealth

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: At least three effective and replicable approaches for increasing demand for LAPMs identified.

Subproject Objective(s): 1) To assess the community perspective of vasectomy, other contraceptive methods, and gender roles surrounding contraception; 2) To describe barriers and facilitators to vasectomy acceptability among vasectomy clients and non-clients, and their wives, including the decision-making process and information sources about vasectomy; and 3) To document the service providers' and policy-makers perceptions of vasectomy, and identify barriers to vasectomy provision.

Description: Despite the many benefits of vasectomy, it remains an under-utilized method of contraception. The primary objective of this research is to replicate and expand upon vasectomy research previously done in Andhra Pradesh, India, and ultimately understand why demand for vasectomy is higher in some districts of India than others. With more specific and actionable data regarding barriers and facilitators to vasectomy, we can establish evidence-based guidelines for improving uptake in other districts and provinces of India, as well as other countries within the region.

Focus groups and both structured and in-depth interviews will be carried out among the following groups in one district with relatively high prevalence of vasectomy and one with low prevalence:

- recent vasectomy acceptors and their wives
- recent tubal ligation acceptors and their husbands (for a comparative sterilization group)
- users of modern contraceptive methods other than sterilization
- vasectomy providers and relevant policy-makers

Additional data collection techniques will include mystery client observation and collection of informational materials surrounding contraception and family planning, including promotional ads, information brochures, and informed consent documents.

The primary outcome of the study will be a comparative in-depth description of knowledge and attitudes about vasectomy among contraception users, community leaders and providers. A secondary output will be a rapid assessment protocol that can be used to document barriers and facilitators to vasectomy provision.

FY Workplan:

- Two study sites and a collaborating agency in India will be identified.

- A protocol will be developed and PHSC and local IRB approvals will be obtained.
- Train local researchers in study methodology.
- Study instruments will be drafted.
- Data collection activities will begin.

Operations Research: Staged Training of Private Sector Midwives To Increase IUD Use

Status: To be approved

Projected End Date: August 31, 2007

Country(ies): Uganda

FCO: TBD

Technical Monitor: J Wesson

Subgrantee: TBD

Collaborating Agency(s): Uganda Private Midwives Association (UPMA), ACQUIRE Project/EngenderHealth, Uganda Ministry of Health (MOH)

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: At least three programmatic approaches to improve service provider performance and client access to LAPMs identified and tested.

Subproject Objective(s): 1) Determine if private providers can be sufficiently motivated by an informational update to subsequently demonstrate client demand for the IUD, as demonstrated by their waiting list/referrals; 2) Determine if technical training of private providers will significantly increase IUD uptake in study areas as compared to control areas; and 3) Determine costs and cost-effectiveness of such an intervention as compared to the typical training methodology of training everyone.

Description: This subproject proposes an innovative operations research activity in partnership with EngenderHealth/ACQUIRE which will test a staggered approach to provider training and client demand creation for IUDs through community-based private midwives. Continuing medical education meetings held by FHI in several districts of Uganda revealed that public and private providers lack up-to-date knowledge on the IUD (and other LAPM) and do not have adequate skills to insert and remove IUDs. They also do not seem to discuss this method with their clients. An inability to identify women interested in the method, a lack of appropriate on-site supervision and follow-up, and a lack of confidence in newly acquired skills are among the most commonly-cited reasons for a drop-off in the number of active providers of LAPMs.

As part of a nationwide revitalization of family planning project, the Uganda Private Midwives Association (UPMA) has requested training for its members on IUD insertion and removal. The UPMA has over 600 members who are distributed over much of the country and provide communities with reproductive health services, including family planning and with maternity and primary health care services. Many UPMA members are the sole accessible service provider for the communities they serve. The UPMA is well organized with regional branches and an established supervision system to ensure quality of care among its members. The ACQUIRE project is proposing to train UPMA members in its four project districts on IUD insertion and removal, demand creation techniques and business skills. Training on IUD insertion and removal is an expensive process, requiring theoretical and practical aspects. It would not be cost-effective to train all the midwives on IUD insertion and removal if they were to follow trends noted in other places and only a few providers used their skills to provide IUD services after the training. This is a problem that many service delivery organizations face: on whom should expensive training resources be expended?

We propose an experiment testing a staged model of training for private sector midwives. UPMA members in test districts will be offered a first stage of training that comprises a knowledge update, including a contraceptive technology update, current national FP guidelines, emphasizing LAPM, and other topics to be determined in collaboration with ACQUIRE and UPMA. Those midwives interested in

obtaining the second-stage technical training in insertion and removal of IUDs will be given a stated period of time to counsel clients in their catchment areas on a range of FP methods, providing clients interested in receiving the IUD with an interim method and placing them on a waiting list for insertion as part of their training program, or referring them to other facilities that are able to provide this method. Public-private partnerships will be explored in this regard. Once a midwife has demonstrated there is an appropriate demand in her community for IUDs, she will attend a centralized training on insertion and removal of IUDs using pelvic models, conducted by ACQUIRE. Subsequent to that training, a practical training will be scheduled in the midwife's regular practice facility, where she will insert IUDs under the supervision of a trainer/supervisor from UPMA. Only after she has successfully inserted several IUDs will she be certified by the UPMA as an IUD provider. Monitoring of IUD services will also be added to the UPMA supervision system.

FY Workplan:

- Complete the research protocol for operations research and obtain ethical approvals at FHI and in Uganda.
- Collect baseline information on the number of IUCDs and other LAPMs being offered in study and control districts; establish a baseline level of quality of care in LAPM provision.
- Conduct a first-stage training/informational update for all UPMA members in selected districts.

Maximizing Access and Quality (MAQ) IUD Subcommittee, and FHI's IUD Checklist Production and Dissemination

Status: To be approved **Projected End Date:** June 30, 2007

Country(ies): Worldwide

FCO: TBD **Technical Monitor:** E. McGinn

Collaborating Agency(s): EngenderHealth/ACQUIRE, INFO Project, USAID, Pathfinder, JHPIEGO, PSI, Population Council, JSI, IntraHealth/Capacity Project

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries.

Subproject Objective(s): 1) To support FHI's participation in a key global technical leadership group that promotes knowledge-sharing and use of best practices related to the IUD; 2) To increase accessibility of key IUD-related resources, including job aids, assessment tools, scientific articles, and advocacy materials for field-based partners; and 3) To increase dissemination and uptake of evidence-based reproductive health practices related to IUD provision (e.g., use of FHI's IUD checklist or other job aids).

Description: Recognizing that access to the IUD has the potential to expand method choice, increase the economic sustainability of family planning programs, and reduce unwanted or mistimed pregnancies, the reproductive health community has increased its focus on revitalizing the IUD. A key component of these efforts is dissemination of accurate programmatic and clinical information on IUD use. To this end, USAID has established an IUD Subcommittee as part of its Maximizing Access and Quality (MAQ) Initiative. Co-chaired by Roberto Rivera (Family Health International, OIRE) and Roy Jacobstein (EngenderHealth/ACQUIRE Project), and with secretariat support from FHI's Research to Practice Initiative, the Subcommittee's mandate is to develop collaborative CA-based projects designed to enhance global IUD use. Its membership includes a wide range of CAs with expertise in training, research, service delivery, advocacy and marketing, logistics, and communications, thus promoting a holistic approach to IUD revitalization.

This subproject will support:

- FHI's participation in the MAQ IUD Subcommittee including ongoing secretariat support and staff participation at MAQ meetings.
- FHI's coordination of the collection and review of documents for an "IUD toolkit". The toolkit is a natural extension of the ongoing work of the Subcommittee and has been identified as a major component of the Subcommittee's workplan for the next two years.
- The compilation/revision/development of FHI's contribution to the IUD toolkit, such as FHI Briefs, PowerPoint presentations, advocacy briefs, assessment tools, and in particular, the development of background information for the FHI IUD Checklist.

FY Workplan:

- Staff will co-chair the USAID MAQ IUD Subcommittee and provide both technical and secretariat support to its activities.
  - ? Development of an electronic "toolkit" of IUD-related jobs aids, curricula, assessment tools, advocacy materials, PowerPoint presentations, country case studies, and key research findings. Once completed, the toolkit will serve as a controlled, accurate, IUD-specific electronic

information resource for the global RH/FP community. Policymakers, program managers, and/or clinical providers and other country-based staff will be encouraged to adapt the contents of the toolkit to meet local needs. The toolkit will ultimately be available in both web-based and CD-ROM versions. Note: The JHUCCP/INFO project will support the development of the electronic interface.

- Develop a reference guide to support use of the FHI IUD Checklist (which will be included in the toolkit). In May 2005, FHI finalized a provider checklist for clients who wish to initiate use of the copper IUD. Rooted in WHO Medical Eligibility Criteria, this checklist provides pertinent questions the provider should ask to safely determine if a woman is eligible to initiate an IUD. This checklist has been field tested, and the findings revealed that while the checklist was comprehensible to providers, it was not easily implemented as a stand-alone product. This suggests that the IUD Checklist would benefit from companion reference material to support its use, and development of this material is to be done with input from the MAQ IUD Subcommittee members.
- Print and disseminate 5,000 of the newly developed (May 2005) FHI IUD Screening Checklist, which serves as a principal component of the IUD Toolkit.
- Develop and disseminate 2,000 informational packages/reference guides to accompany the IUD Screening Checklist
- Participate in a MAQ IUD Subcommittee sponsored panel (accepted) at APHA 2005.

Global Advocacy & Stakeholder Engagement for LAPMs

Status: To be approved **Projected End Date:** June 30, 2007

Country(ies): Worldwide

FCO: 113109 **Technical Monitor:** E McGinn

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.

Subproject Objective(s): 1) To broaden advocacy messages beyond IUDs, and to ensure that "Repositioning Family Planning" efforts include a revitalization of LAPMs based on evidence and best programming practices; and 2) To engage in-country stakeholders on revitalization of LAPMs and support champions for south-to-south learning of best practices on LAPM revitalization efforts.

Description: Despite a continued unmet need to both space and limit births, only half of 91 developing countries – and only four of 30 in sub-Saharan Africa – have made available at least one LAPM method and at least one short-term method to family planning clients. LAPMs can play a significant role in addressing unmet need and contraceptive choice, and as such, can strengthen the public health impact of family planning programs. The IUD provides clients with a highly reliable, safe, and cost-effective method of family planning appropriate for both limiting and spacing births. Vasectomy offers similar benefits in terms of effectiveness and safety and can be promoted in the context of male involvement. Although female sterilization is a popular and accessible method in many places, there continues to be an unmet need for it in Africa. Also, the development of new implants presents future challenges and opportunities for family planning programs.

Essential steps in achieving FHI's LAPM Strategy outcomes are promotion of research results and advocacy for changes in policies and programs. In order to achieve "*evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries*," FHI must first undertake a cohesive strategic effort to identify and map opportunities to influence key US-based CAs, USAID missions, ministries of health, and in-country stakeholders (such as local NGOs/PVOs/CAs and professional associations). FHI then must subsequently engage in both global and country-specific advocacy efforts to reach these key change agents in hopes of generating (or reinforcing) interest in LAPMs and building momentum and consensus to revitalize LAPMs. We must offer technical assistance in adapting findings and implementing policy and programmatic changes. **While FHI has spearheaded focused efforts to initiate global attention to IUDs, a broader program to emphasize LAPMs more generally has advantages that can complement more method-specific efforts. This subproject will be the primary vehicle through which the conceptualization and initiation of a broader LAPM advocacy effort will be accomplished.** Where desirable, activities under this subproject will be coordinated with or offer technical assistance to FHI's *Enhanced Country Program* and LAPM subprojects at the country level. This subproject will also coordinate with and complement existing efforts to revitalize the IUD by the MAQ IUD Subcommittee.

FY Workplan:

- Develop a global FHI LAPM advocacy strategy for 2006 – 2008, to include global/HQ activities, focus-country activities, and a monitoring and evaluation plan to determine the impact of LAPM advocacy and stakeholder engagement activities under the CRTU.
- Monitor activities on "Repositioning Family Planning," particularly among West African countries, to ensure LAPMs are on the agenda; organize presentations/posters for any follow-on or related meetings in 2005-2006.
- Support presentations on LAPMs at one global meeting, and one regional or country meeting on family planning and reproductive health. Emphasis will be on opportunities for South-South sharing of experiences.
- Liaise with researchers to identify promotion and advocacy needs for forthcoming research on implants (Jadelle/Implanon) and nonsurgical female sterilization.
- Collaborate with Information Programs on synthesis and dissemination of recent/ongoing LAPM research at the global level.
- Plan for an early 2007 South-South meeting on LAPMs in Africa. Several African countries are currently engaged in LAPM revitalization activities and many others are looking at LAPMs (particularly IUDs) and are anxious to learn from existing programs. A South-South meeting would enable country teams to develop strategies to initiate implementation of new information or undertake new activities. Planning and sourcing for partners and additional funds for such a meeting would be initiated under this subproject.
- Where funds permit, provide technical assistance to FHI's *Enhanced Country Program's* advocacy efforts, such as assistance with developing advocacy strategies, adapting advocacy/IEC materials, or reviewing national guidelines.

Repositioning Family Planning: Revitalizing LAPMs in Uganda

Status: To be approved **Projected End Date:** June 30, 2006

Country(ies): Uganda

FCO: 113110 **Technical Monitor:** E McGinn

Collaborating Agency(s): Uganda Ministry of Health, ACQUIRE/EngenderHealth, other in-country partners.

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.

Subproject Objective(s): 1) To provide technical assistance and support to the Uganda MoH in order to mobilize in-country stakeholders to undertake a revitalization of long-acting and permanent methods, particularly the IUD; and 2) To provide technical assistance to the MoH and in-country partners (e.g., ACQUIRE/EngenderHealth) in implementing evidence-based LAPM activities, and adapting/implementing lessons learned from the Kenya IUD Rehabilitation Initiative 2002-2005.

Description: Ever use of contraceptives by women in Uganda increased four-fold between 1988 and 2001, from around seven percent to 35 percent. Today, pills, condoms, and injectables dominate the method mix, and fewer than seven percent of contraceptive users have ever used IUDs, female sterilization, or vasectomy. Yet around a quarter of urban women, and a third of rural women, indicate an unmet need to space or limit births.

In response to these needs, this subproject will engage in LAPM activities (focused on the IUD) in Uganda. These are considered continuing activities which were initiated in January 2005, when the Ministry of Health (MoH) requested FHI's technical assistance with expanding IUD access in Uganda, in collaboration with EngenderHealth's ACQUIRE Project (which received funding in October 2004 to undertake IUD revitalization activities within the context of promoting longer term and permanent methods). In the past six months, FHI initiated this collaboration by: (1) providing assistance to the MoH to establish a national "Repositioning Family Planning Working Group," composed of in-country stakeholders and EngenderHealth/ACQUIRE and FHI; (2) developing an addendum to the 2001 national family planning guidelines providing an evidence-based update on eligibility criteria for all methods; and (3) providing technical assistance to EngenderHealth on costing and monitoring and evaluation of their LAPM activities in the district of Mayuge, which will inform scale up in other districts.

The process thus far is adapting lessons learned from FHI's experience in Kenya and capitalizing on relationships with FHI's CRTU Memorandum of Understanding partners (EngenderHealth, Save the Children, ADRA, INFO, PATH, Population Council) and other partners to instigate a stakeholder engagement and consensus-building process that can leverage various partner activities to respond to MoH priorities and improve family planning programs in Uganda. Mission funds have not been offered for these activities conducted by FHI, but the Mission has contributed to LAPM revitalization activities undertaken by ACQUIRE. FHI has not had a significant presence in Uganda in the past and will leverage the activities under this subproject to explore Mission interest in ongoing support for FHI's efforts in FY 06-07. If none are forthcoming, this subproject's activities are self-contained within a one-year time frame and no further investment in this activity in Uganda will be required. However, if Uganda becomes one of the CRTU's Enhanced Countries, this subproject will serve as an entry point and platform for the development of future activities.

FY Workplan:

- Staff will continue to support the MoH in its efforts to coordinate the Repositioning Family Planning Working Group.
- Staff will provide technical assistance to the MoH: 1) development of a national strategy on repositioning family planning with an LAPM component; and 2) adaptation of Kenya's lessons learned/creative approaches on IUD revitalization for use in Uganda.
- Effort will be made to strengthen partnerships with Working Group members (EngenderHealth/ACQUIRE, UPHOLD, others) by identifying and initiating at least one joint activity (e.g., development of advocacy materials).
- Staff will finalize and print the Eligibility Criteria addendum to the National FP Guidelines.
- Staff will engage professional associations through five continuing professional development workshops in targeted districts, and promotion/dissemination of up-to-date evidence on vasectomy, the National Guidelines addendum, FHI's IUD Checklist, and the MAQ IUD Toolkit CD-ROM (forthcoming).
- Operationalization of FHI's MoU with EngenderHealth will be completed through continued technical assistance with analysis of cost data collected in Mayuge and adaptation of the costing instrument for scale-up two other districts.
- Monitoring and evaluation of FHI's process efforts in Uganda will take place to determine their impact on mobilizing support for LAPM revitalization.
- Monitoring and evaluation of the continuing professional development workshops will take place to determine impact on providers' interest in LAPMs.

These activities will be coordinated with other Uganda-related concept proposals, including an HSR Operations Research on training of midwives, the Research to Practice *Network of Champions* (Uganda) if applicable, and the Research to Practice *Advocacy & Stakeholder Engagement for LAPMs.*

Kenya IUD Revitalization – Transition Phase and M&E

Status: To be approved **Projected End Date:** June 30, 2007

Country(ies): Kenya

FCO: 113111 **Technical Monitor:** E McGinn

Collaborating Agency(s): Kenya MoH, AMKENI, EngenderHealth/ACQUIRE, Marie Stopes, professional associations, other local stakeholders.

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.

Subproject Objective(s): 1) To develop and implement FHI's exit strategy from the Kenya IUD Revitalization Initiative (ongoing); 2) To provide technical assistance to the Kenya MoH and other partners during the leadership transition; 3) Focused advocacy and outreach at the national level to program managers and professional associations to disseminate the new Kenya FP Guidelines and FHI's IUD Provider Checklist; and 4) To ensure ongoing monitoring and evaluation of the Kenya IUD Reintroduction experience.

Description: In 1989, a fairly balanced method mix was in use in Kenya, with over one quarter of women ever using an IUD, around 15 percent ever using condoms, around 15 percent choosing sterilization, and around two-thirds of women ever using pills. By 2003, the method mix in Kenya had changed substantially. Ever use of pills decreased to 56 percent of women, and ever use of IUDs and female sterilization plummeted to 13 percent and seven percent respectively. This skewed method mix was not only unsustainable for the Kenya Ministry of Health (injectables are far more expensive than IUDs and sterilization), but also not entirely reflective of changing consumer preferences. According to a 1995 study on the decline of IUDs in Kenya (Stanback et al.), provider bias, fear of HIV, and logistical issues played a tremendous role in client uptake of methods.

In 2002, the Kenya Ministry of Health initiated a national effort to improve contraceptive choice and promote a sustainable method mix, with a focus on revitalizing IUD use, termed the Kenya IUD Rehabilitation Initiative. In addition to providing technical support and capacity development to the MoH, FHI has collaborated with several partners on this activity, including AMKENI (EngenderHealth-led bilateral), JHPIEGO, DFID, Kenya Obstetrics and Gynecology Society, Family Planning Association of Kenya, GTZ, PRIME/INTRAH, Africa Population Advisory Committee, and the Population Council. FHI and AMKENI have successfully increase IUD use in pilot sites by approximately 200% (see FCO 3022/3432 under the CTR). Now, several organizations are scaling up the service delivery and demand creation components of the IUD Rehabilitation project. For example, EngenderHealth has received funding to expand IUD services to non-AMKENI sites, and Marie Stopes is experimenting with social marketing/franchising of IUD supplies and services.

Under this subproject, FHI will develop and implement its exit strategy. FHI has played a pivotal secretariat and coordinating role for the MoH and partners. As IUD rehabilitation in Kenya becomes main-streamed, FHI will focus its attention on technical assistance and monitoring and evaluation. Of particular need, is evaluation of the impact thus far at a national level (adequate data is already available for the AMKENI sites).

FY Workplan:

- Staff will provide technical assistance to MoH and partners to develop a national plan for scale-up and leadership transition.
- Staff will serve as secretariat for the MoH IUD Working Group and IUD Rehabilitation Initiative for its final year, as leadership transition is established.
- Staff will provide technical assistance to the Provincial Medical Officer in Western Province to implement detailing as a model of supportive supervision.
- Staff will disseminate the new Kenya FP Guidelines and FHI's IUD Provider Checklist at the national level to program managers and professional associations.
- Staff will print and disseminate the Kenya IUD Rehabilitation Initiative Booklet which documents the process and results of the effort 2002-2005.
- There will be continued monitoring and documentation of outcomes of IUD efforts.
- Staff will design an impact evaluation of IUD efforts in non-AMKENI sites (evaluation to take place FY 06-07).

USAID Financial Support to Develop a Method of Female Nonsurgical Sterilization with Erythromycin

Status: To be approved **Projected End Date:** April 28, 2010

Country(ies): U.S.

FCO: 112107 (previously FCO 2271) **Technical Monitor:** A Cancel

USAID Intermediate Objective to be addressed: IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: To develop a safe, effective, and acceptable method of non-surgical female sterilization ready for introduction into FP programs within ten years.

Subproject Objective(s): To cost-share activities funded by a private foundation.

Description: Under this subproject, USAID will provide financial support to offset the G&A costs that are above the 15% currently paid by our primary donor for five subprojects. These subprojects include activities related to: 1) the development of erythromycin as a means of female nonsurgical sterilization [chemistry manufacturing and controls, preclinical (development and toxicology activities), regulatory, social sciences, communication initiatives, licensing opportunities evaluation, patent activities and clinical activities]; and 2) the operations of a consumer advisory committee which provides oversight of the overall female nonsurgical sterilization program. This would continue an agreement reached under the CTR whereby FCO 2271 served in the same way.

FY Workplan:

- Expenses will be transferred as costs are incurred for the above mentioned projects.

Operations Research: Male Motivators Promoting Family Planning in the Nigeria Police Force

Status: To be approved **Projected End Date:** August 31, 2007

Country(ies): Nigeria

FCO: TBD **Technical Monitor:** J Wesson

Subgrantee: TBD

Collaborating Agency(s): Nigeria Police Force, Integrated Reproductive Health Program; GHAIN/FHI; COMPASS/Pathfinder; EngenderHealth

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Evidence provided from two or more demonstration projects (in partnership with service-delivery organizations) on effective approaches to increasing male involvement in family planning (FP) and uptake of vasectomy.

Subproject Objective(s): 1) To evaluate whether male peer education successfully: (a) improves knowledge and attitudes about FP and HIV risk-reduction behaviors among uniformed services; and (b) increases FP uptake among police officers and their families; and 2) to create integrated FP/HIV peer education curriculum for male members of uniformed services.

Description: The International Conference on Population and Development (ICPD) Program of Action states that involving men in reproductive health should receive special effort to promote uptake of family planning and gender equality. In many societies, men prevent their wives from using FP by denying them permission for or the ability to access services. Vasectomy is one of the least expensive, least complicated and most effective methods of family planning, yet men in most countries continue to be reluctant to undergo the procedure. In almost every region of the world, members of the uniformed services (military and police) have been targeted recently for HIV prevention programs, but there are few examples in the literature of promoting FP among these populations. Of those that exist, good measurement and evaluation of impact has not taken place. Identifying and targeting a police force offers access to a large audience that is predominantly male, married and not engaging in family planning. In addition, conducting operations research in such a population will help build the evidence base for male involvement programs, particularly with uniformed populations.

The Nigeria Police Force offers a unique opportunity to test a peer education intervention for reproductive health. The Force has over 175,000 men and women serving in every region of Nigeria. Police personnel and their families/dependents are estimated at close to 1,000,000 people. According to the Force Medical Service, police tend to have large families and as a highly mobile group, also tend to engage in high risk sexual activities. We propose to work with the Nigeria Police Force Integrated Reproductive Health Program to update the male motivators' curriculum with the latest information and messages about FP methods, particularly LAPM, and to train male motivators using this curriculum. Police officers who are satisfied family planning users will be recruited to serve as male motivators. Motivators will also be trained to counsel on HIV risk reduction, supply condoms and provide referrals for facilities equipped to provide specific FP methods. The subproject will take place in conjunction with clinical support for RH and HIV programs provided to the Police Force by FHI (GHAIN project) and Pathfinder (COMPASS project). The EngenderHealth Men as Partners (MAP) program will assist in updating the training curriculum.

The study will designate a convenience sample of intervention and control sites in areas that have Force Medical Service clinics with functioning FP services. To evaluate the program, knowledge and attitudes about FP and HIV risk-reduction behaviors and uptake of FP in Force Medical Service clinics will be measured pre- and post-intervention.

FY Workplan:

- Complete a research protocol for operations research and obtain ethical approvals at FHI and in Nigeria.
- Produce an updated, integrated male motivators curriculum in collaboration with EngenderHealth.
- Conduct a baseline survey of police officer and family member knowledge and attitudes about FP and HIV risk-reduction behaviors; establish baseline uptake of FP in Force Medical Service clinics.

Vas Irrigation with Diltiazem

Status: To be approved **Projected End Date:** April 30, 2006

Country(ies): Worldwide

FCO: 112113 (formerly 2261 and 2707) **Technical Monitor:** D Sokal

Subgrantee: Vimta Laboratories, Hyderabad, India

Collaborating Agency(s): TBD

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: At least one spermicidal agent that could prove effective in hastening azoospermia after vasectomy evaluated.

Subproject Objective: To complete a Good Labor Practices study in rabbits of the local toxicity of diltiazem administered into the vas at various dosages, and to finalize a report describing the results of the study.

Description: Vasectomy is one of the safest and most reliable forms of contraception, but there is a risk of pregnancy in the immediate post-vasectomy period due to residual, down-stream sperm. An FDA-approved method of vas irrigation could decrease the risk of pregnancy in the immediate post-vasectomy period and improve the acceptability and uptake of vasectomy services.

This subproject funds the continuation of an activity begun under the CTR. Based on a pre-IND meeting with the FDA, this GLP study in rabbits is a pre-condition to a Phase I study of diltiazem in men undergoing vasectomy. If funding were available to go forward, this study could be followed by an IND submission to the FDA for a Phase I, dose-escalation study of diltiazem among men undergoing vasectomy in the US.

This GLP study has the following main components: Anesthetized rabbits in the test groups and vehicle control group will be vasectomized, and diltiazem or saline will be directly administrated into the lumen of the posterior region of vas. Reproductive tissues will be collected, preserved and examined microscopically to evaluate the local effects if any of diltiazem. Further, to understand pharmacokinetics of diltiazem, serial blood samples will be collected from a subset of the rabbits.

FY Workplan:

- A final report from a GLP study in rabbits of the local toxicity of diltiazem administered into the vas at various dosages will be prepared.

STRATEGY
Male and Female Barrier Methods

With the subprojects proposed under the male and female barrier methods strategy, each of the above goals is addressed. Three address goal I, eight address goal II and two address goal III.

GOALS	OUTCOMES
I. To bring to market new female barrier methods that are effective for dual protection and are affordable, acceptable, and conducive to widespread uptake and sustained use.	A. At least two lower cost female condom models assessed for safety, effectiveness, and acceptability. B. A new, less expensive female condom submitted to the FDA for marketing approval. C. At least one promising new diaphragm evaluated for contraceptive effectiveness and/or prevention of sexually transmitted infections (STI). D. A pre-marketing approval application (PMA) for a new diaphragm submitted to the FDA. E. Innovative research methodologies that lower the cost and speed the pace of bringing new products to market developed and validated.
II. To increase the use of existing barrier methods, and other risk reduction behaviors, by achieving greater acceptance on the part of users and service providers.	A. Cost and effectiveness of alternative ABC delivery models targeting youth (including communication channels, messages, parental/adult involvement, community support, and collaborating partners) evaluated and applied in at least three countries. B. Training and supervision approaches and job aids that heighten providers' capacity to promote barrier methods (most immediately, male and female condoms) to family planning clients developed, tested and implemented in at least five countries. C. Evidence-based counseling approaches for male and female condom promotion incorporated into family planning service guidelines, including those used by HIV/AIDS programs (VCT, ART, PMTCT) in up to six countries. D. Research necessary to effect policy change and acceptance of female condom reuse among providers and local governments completed, with results incorporated into policies and service delivery guidelines. E. Feasibility, cost, and effectiveness of alternative male and female condom distribution mechanisms assessed. F. Evidence regarding the effectiveness of female barrier methods disseminated to policy makers to influence procurement and programming decisions. G. Evidence-based strategies to increase use of barrier methods for contraception by couples with at least one HIV+ partner developed, evaluated and implemented. H. Approaches for overcoming male resistance to male condom use, informed in part by "exemplars" who succeed in using condoms more often than the norm, documented and replicated. I. Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated.
III. To make safe and effective RH products available in an efficient and less costly manner.	A. An ISO standard for synthetic male condoms and female condoms established. B. Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Next Steps for Clinical Research of New Female Condoms

Status: To be approved **Projected End Date:** February 28, 2007

Country(ies): Several developing countries TBD (suggested India, Madagascar, South Africa)

FCO: 112111 **Technical Monitor:** C Joanis

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: At least two lower cost female condom models assessed for safety, effectiveness, and acceptability.

Subproject Objective(s): 1) To complete a plan of action to proceed with the research on new FCs; 2) To select the best candidate(s) female condom to distribute in public sector programs; 3) the determine public-sector pricing for the three female condom types; and 4) to provide bio-statistical input into the development of international standards for female condom products.

Description: Providing FCs for pregnancy and HIV prevention is a priority for USAID. Reality® (FC1), approved by the FDA in 1993, is sold globally but sales are limited by its high price--20 times that of a male condom. A goal of USAID is to develop a low cost female condom that is equivalent to FC1. The three condoms studied in this subproject are: FC2, Reddy 6 and the PATH Woman's Condom. The subproject will cover four areas:

Strategy: We will write a strategy for studies of FCs. Our strategy will use decision points to select one product that is preferred by users (best candidate product for promotion and use in developing country programs).

Price Quotes: We will help FC manufacturers develop cost analyses to support public-sector price quotes. The analyses will support our strategy and influence our suggestion to continue or discontinue study of a particular FC type.

Research: Our study will pin/point slight variations in user preference and device performance of the three condom types. Past studies of FC function and acceptability used designs and analytical methods that have not clearly shown a market leader. Thus, our surveys and methodology will be more market-specific and qualitative than bio-statistical. Following product testing by FHI's Product Quality and Compliance group, the study will be conducted in several developing countries (TBD). Women will use 3-5 devices of each FC and complete a survey after using each type. We will use market research analyses to detect subtle differences in preference between devices. Participants will choose 10 free FCs at the end of the study. A choice of free FCs will support preference data. Some women will be asked to take part in in-depth interviews.

Support at ISO: An FHI bio-statistician will attend meetings of the ISO Female Condom Working Group to provide input into the development and testing of international standards of manufacture for FCs, including clinical performance indicators for new products.

FY Workplan:
- An FHI biostatistician will attend the Annual ISO Female Condom Working Group meeting. The meeting will be held in Berlin in September 2005.
- An organization and planning meeting will be held with CONRAD and USAID in September 2005. Decisions made at this meeting will provide guidance for the development of the FC Strategy and future research direction.

- Potential study sites will be contacted in late November 2005.
- Subagreements for the study sites will be developed in December 2005 and finalized in January 2006.
- A protocol and related study instruments will be developed in October and November 2005.
- The protocol and related instruments will be submitted for PHSC and local IRB approvals.
- PQC will test products for quality assurance against manufacturer specifications.
- Import/export approvals will be obtained if needed.
- Site visits will be made in January and February 2006.
- The research study will be initiated between March and April 2006.

Comparative Study of PATH's Soft-Cling Woman's Condom (WC) and the Female Condom (FC)

Status: Ongoing **Projected End Date:** June 30, 2006

Country(ies): USA

FCO: 112102 (Previously FCO 2287) **Technical Monitor:** G Pittman

Collaborating Agency(s): CONRAD

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: At least two lower cost female condom models assessed for safety, effectiveness, and acceptability.

Subproject Objective(s): To provide statistical and data management support to a CONRAD study designed to assess the functional performance, safety and acceptability of the PATH Woman's Condom (WC) compared to the Reality Female Condom (FC).

Description: This subproject is a continuation of a Phase I, comparative, crossover study that was done under the CTR at three sites, with a substudy at one of these sites using colposcopic assessment (FCO 2287). Recruitment included 75 couples at low risk for STIs and protected against pregnancy through use of reliable (non-barrier) contraceptive methods. Couples had to be in monogamous relationships for 3 months prior to enrollment and throughout the study. The couples were randomized to a female condom sequence (WC/FC or FC/WC). At all sites, couples were to use 4 condoms of each type at home in 4 acts of intercourse over a 2-4 week period. After a follow-up visit, these procedures were to be repeated with the second condom type. At one site (n=25), one condom of each type was to be used for fit assessment, a baseline colposcopy performed, and each condom type will be used with simulated intercourse followed by colposcopic evaluation.

NOTE: In December 2004, the protocol was amended to change the colposcopy substudy. It was discovered that simulated intercourse posed technical problems during testing, and actual intercourse was to be used instead. A baseline colposcopy was to be done prior to the first condom use of each of the 2 condom types. The couples were to use the condom for the first act of intercourse within 72 hours of the baseline colposcopy; the female participant was to return for a follow up colposcopy within 6 hours of intercourse.

This study is a continuation of work begun under the CTR Program (FCO 2287).

FY Workplan:
- Data entry and querying will be completed.
- Table shells and the analysis plan will be finalized.
- A preliminary table for functionality will be prepared for CONRAD to present at a meeting on the female condom in September 2005.
- The statistical report will be completed and submitted to CONRAD.
- FHI will review the final clinical report as requested.
- The study will be archived.

Phase III Effectiveness Study of PATH SILCS Diaphragm

Status: To be approved **Projected End Date:** June 30, 2008

Country(ies): USA (sites TBD)

FCO: 112101 (Previously FCO 2299) **Technical Monitor:** G Pittman

Collaborating Agency(s): CONRAD

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: At least one promising new diaphragm evaluated for contraceptive effectiveness and/or prevention of sexually transmitted infections (STI).

Subproject Objective(s): To provide data management, statistical analysis, regulatory audits, and monitoring of assigned sites for this CONRAD Phase III study designed to assess the effectiveness of the SILCS diaphragm in preventing pregnancy.

Description: This multi-center, single-arm contraceptive effectiveness study of SILCS diaphragm used with 2% N-9 will assess and compare the contraceptive effectiveness of the SILCS diaphragm with that from women who received the Ortho All-Flex® diaphragm in the FemCap/diaphragm pivotal study (historical controls). In this study, approximately 400 women at risk for pregnancy with no contraindications to the use of a diaphragm will be recruited at about 8 study sites. To the extent possible, sites will be selected among those centers which participated in the FemCap/diaphragm study. Each participant will agree to use the SILCS diaphragm with 2% N-9 as her only method of contraception for 28 weeks. In addition to the 400 women in the main study, 80 (40 at each of 2 sites) women will be recruited for a substudy collecting colposcopy and microflora specimen data. Women in the substudy will be randomized to receive either the SILCS diaphragm or the Ortho All-Flex diaphragm (concurrent controls). Such a substudy is needed because progress made in colposcopy makes it difficult to collect data comparable to the historical control group and because of the lack of data for microflora evaluation in the historical control group. In order to facilitate the planned historical control analysis, the substudy design and data collection methods will conform to that of the FemCap/diaphragm pivotal study (historical control).

This study is a continuation of work begun under the CTR (see FCO 2299).

FY Workplan:
- Biostatistics and Data Management staff will work with the CONRAD project leader to develop and finalize the case report forms.
- Data Management will set up the data entry protocol in ClinTrial.
- Biostatistics and Data Management staff will work together to prepare data cleaning specs, program them into ClinTrial, create test data, and validate the ClinTrial system for this study.
- The FHI clinical monitor will provide input and feedback to the CONRAD monitor in the development of the study manual.
- The FHI monitor will work with the CONRAD monitor to initiate the study at all the sites, beginning in March 2006.
- Data entry and the querying process will begin.

Testing the ABC Approach Among Kenyan Youth in Institutions of Higher Learning

Old Title: Testing the ABC Approach Among Youth at Institutions of Higher Learning and Testing the ABC Approach Among University Students

Status: Ongoing

Projected End Date: June 30, 2006

Country(ies): Nairobi, Kenya

FCOs:
FCO 9493
FC0 153100

Technical Monitor:
S. Thomsen
C. Jagemann

Subgrantee: I Choose Life (ICL)

Collaborating Agency(s): University of Nairobi (UON)

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and **Expanded**

Strategy Outcomes(s) to be addressed: Cost and effectiveness of alternative ABC delivery models (including communication channels, messages, parental/adult involvement, community support, and collaborating partners) targeting special groups like men and youth evaluated and applied in at least three countries.

Subproject Objectives: 1) To test an enhanced strategy for promoting ABC messages as a means of reducing risky sexual behaviors among first-year university students in comparison with an existing peer education program. This objective will be achieved by examining changes in levels of self-reported abstinence, (both primary and secondary), partner reduction and mutual monogamy. Secondary objectives include: 1) to evaluate student's recall, comprehension and reactions to ABC messages; and 2) to document outputs such as number of people reached by the intervention**.**

Description: This study/intervention will inform policy makers and program managers on: 1) the effectiveness of an A-B-C peer education/mass communication approach on increasing protective sexual behaviors among university students; 2) the need for adjustments in future programming; and 3) the challenges that are involved in executing such a program. It became apparent during Phase I that students need specific skills-based training in order to negotiate and maintain abstinence, being faithful to a single partner, and for condom use when appropriate. This second phase will address this need with an enhanced skills-based training for the peer educators.

This is a quasi-experimental study with a control group using a cross-sectional, pre-post design. The intervention consists of peer education (with the enhanced skills training) and campus-wide information campaigns through two enter-educate events. The peer educators will work with university students in small behavior change communication groups, assisting them to develop the necessary, practical skills to use ABC for infection protection. An advisory committee will meet quarterly to help guide all intervention activities, alerting project staff to potential challenges and proposing appropriate solutions.

I Choose Life (ICL), has about 50 full time staff and has trained over 500 peer educators at the UON (150 of these currently active) and will continue to train students during the second phase of the subproject and provide supervision as they work in the BCC groups with the university students. ICL will also organize and run the enter-educate events and collect necessary study data which will be maintained and

interpreted in the FHI offices in Nairobi. FHI Nairobi and NC will provide oversight and technical assistance.

Process data, including the number of peer educators trained in AB, the number of students reached through peer education efforts, and the number reached through media efforts will be collected through the life of the intervention. These indicators are consistent with the required PEPFAR indicators. Additional qualitative information on key topics discussed, issues raised, resolutions reviewed on a quarterly basis. Programmatic adjustments will be implemented.

This study is a continuation of work begun under the CTR Program (FCO 9493). This FCO will continue under the CRTU as it finds an activity approved by USAID under the No-cost Extension.

Outreach Targets

- Number of mass media HIV/AIDS prevention programs that promote abstinence and/or being faithful. Target: 2 major enter-educate events/programs
- Number of individuals reached with community outreach HIV/AIDS prevention programs that promote abstinence and/or being faithful. Target: 2,500
- Estimated number of individuals reached with mass media HIV/AIDS prevention programs that promote abstinence and/or being faithful. Target: 5,000
- Number of individuals trained to provide HIV/AIDS prevention programs that promote abstinence and/or being faithful. Target: 200

FY Workplan:

- A post intervention questionnaire will be administered.
- A Life Skills curricula will be developed .
- A refresher training for Peer Educators from Phase I will be conducted.
- A Life Skills training for Peer Educators will be conducted.
- Two major Enter-Educate events will be conducted.
- 100 BCC groups will be formed by peer educators.

ABC Approach for Youth on University Campuses in South Africa

Status: To be approved **Projected End Date:** June 30, 2006

Country(ies): South Africa

FCO: 153101 **Technical Monitor:** C Jagemann

Subgrantee: None

Collaborating Agency(s): UNFPA, South African Centre for Organizational Development (SACORD); Association of Catholic Tertiary Students (ACTS)

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Cost and effectiveness of alternative ABC delivery models (including communication channels, messages, parental/adult involvement, community support, and collaborating partners) targeting special groups like men and youth evaluated and applied in at least three countries.

Subproject Objective: To reach university students with appropriate ABC messages to reduce their risk for sexually transmitted infections, including HIV, and unintended pregnancies.

Description: Students on four South African university campuses will be the focus of the media and peer intervention. The media component will consist of a five-episode radio series aired on campus stations, as well as on others in the communities around the universities. The series will highlight reproductive health issues and ABC to overcome perceived barriers to risk reduction. The enhanced peer education component will focus on life skills, self-esteem, gender equity, and specific communication/negotiation skills to increase ABC behaviors. Twenty-five peer educators per campus will be trained to mentor other university students in small groups. The peer educators will be supervised by the project coordinators, who are affiliated with the office of HIV/AIDS on each of the university campuses. Additionally, a National Student Academy will be organized to provide an opportunity for peer educators in other Universities in South Africa to benefit from lessons learned through the ABC intervention.

Process data, including the number of peer educators trained in AB, the number of students reached through peer education efforts, and the number reached through media efforts will be collected through the life of the intervention. These indicators are consistent with the required PEPFAR indicators. Additional qualitative information on key topics discussed, issues raised and resolutions will be reviewed on a quarterly basis. Programmatic adjustments will be implemented.

FY Workplan:

- Life Skills curricula will be developed.
- Life Skills training for Peer Educators will be conducted.
- A five-episode radio series will be produced and aired.
- 100 BCC Groups will be formed by peer educators.

Structural Integrity of the FC2 Female Condom: Assessment of Potential for Reuse

Status: To be approved

Projected End Date: January 31, 2006

Country(ies): US

FCO: 112117

Technical Monitor: C Joanis

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Research necessary to effect policy change and acceptance of female condom reuse among providers and local governments completed, with results incorporated into policies and service delivery guidelines.

Subproject Objective(s): To determine the feasibility of reusing the new FC2 female condom. We will compare the test values obtained at baseline and after each wash/bleach sequence (1X, 2X, etc.) with the manufacturer's specifications for water leakage, tensile strength and tear propagation. By comparing these values, we will determine whether the detergent and disinfectant have any impact on the structural integrity of the female condom. Findings will be presented along with other recently completed female condom reuse data to members of the WHO panel on female condom reuse. Depending on results, new guidance may have to be written concerning female condom reuse when the FC2 becomes available.

Description: A prototype female condom (FC2), made of a synthetic polymer (synthetic latex) and meeting the same structural specifications as the polyurethane female condom (FC1), has been developed by the Female Health Company. The major advantage of FC2 over its predecessor is cost, ~$0.25 vs. $0.74, respectively (public sector pricing). Data on the comparative performance of FC1 and FC2 (study conducted in South Africa) has been submitted to the FDA for review. Determination of approval or need for further research is expected in September 2005. While FC2 will be much less expensive than FC1, its projected public sector price is still 4-5 times the cost of a male latex condom. In relation to its indication for one time use, donors may still be reluctant to purchase and supply the device.

Earlier research conducted by FHI and the RHRU (South Africa) showed that it was possible to reuse the FC1 multiple times. Given the successes shown in cleaning the FC1 and the fact that the FC2 device is still far more expensive than a male latex condom, there is a need to conduct research to assess the reuse potential of this new product. Since the FC2 material is a proprietary polymer, there is no published information and no one has conducted research to assess the impact of detergents and disinfectants on the materials' structural performance. Such information may be used to provide guidance on cleaning the female condom and result in the provision of a female condom product that can be cost-competitive with male condoms.

FY Workplan:
Staff will:

- modify the existing structural integrity protocol to assess feasibility of reuse of the FC2 female condom (September 2005),
- order FC2 female condoms from the Female Health Company (September 2005),
- get on the testing schedule at PQC (September 2005),
- conduct baseline testing of devices (October or November 2005), and
- conduct reuse (washing in detergent and bleaching) testings (November 2005).
- PQC testing report will be completed (December 2005).
- The final presentation and/or report will be drafted (January 2005).

Measuring Effectiveness of UNFPA-sponsored Female Condom Promotion Initiatives

Status: To be approved

Projected End Date: June 30, 2006

Country(ies): Worldwide

FCO: 114107

Technical Monitor: T Hoke

Subgrantee: N/A

Collaborating Agency(s): UNFPA

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Feasibility, cost, and effectiveness of alternative male and female condom distribution mechanisms assessed.

Subproject Objective(s): 1) To collaborate with UNFPA in developing a protocol for measuring the relative cost-effectiveness of alternative female condom distribution systems; and 2) to devise a plan for UNFPA-funded technical assistance in M&E.

Description: UNFPA is currently launching an initiative in 22 countries worldwide to strengthen country capacity to introduce or re-introduce female condom programming. Countries will have the latitude to position female condom distribution according to their own needs and resources; it is anticipated that distribution will take a variety of forms within public- and NGO-sponsored family planning, HIV/AIDS, and STI programs. UNFPA's multi-country initiative creates an opportunity for FHI to assess the feasibility, cost, and effectiveness of alternative female condom distribution mechanisms. Through this subproject, which supports study design, FHI will gather information about the spectrum of UNFPA-supported female condom programs in order to select sites and devise a technically sound protocol for an investigation of the relative cost-effectiveness of alternative distribution models. Data to be gathered in the protocol development phase will focus on issues such as the objectives, scope, and scale of distribution programs in different countries; possible mechanisms for monitoring female condom distribution at the central level and uptake at the facility level; possibilities for assessing changes in dual protection behaviors in response to female condom promotion; opportunities for collecting cost data; willingness of country partners to collaborate on this assessment; and the information needs of national and international decision-makers relative to female condom distribution models. Based on this data, FHI will prepare a protocol for a comparative assessment of female condom distribution programs, to be initiated in Year 2 of the CRTU.

Additionally, UNFPA has indicated funds are likely to be available in Year 2 to support FHI technical assistance for country-level monitoring & evaluation of male and female condom distribution programs. This subproject will support development of FHI's plan for offering such TA.

FY Workplan:
- A study protocol will be developed, with technical and ethical approvals secured.
- A memoranda of understanding will be established with at least 2 country partners.
- A proposal for M&E technical assistance will be prepared.

Global Consultation on the Female Condom

Status: To be approved **Projected End Date:** June 30, 2006

Country: Worldwide

FCO: 113100 **Technical Monitor:** K. Shears

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
- Evidence regarding the effectiveness of female barrier methods disseminated to policy makers to influence procurement and programming decisions.
- Evidence-based counseling approaches for male and female condom promotion incorporated into family planning service guidelines, including those used by HIV/AIDS programs in up to six countries.

Subproject Objective(s): 1) To prepare a joint media and dissemination strategy with key CA partners in preparation for Global Consultation on the Female Condom (GCFC); 2) to participate in the GCFC, providing technical input on current knowledge; and 3) to implement follow-up dissemination activities to increase access, among key developing country audiences to current female condom research.

Description: The female condom is intended to serve a dual role, offering protection from pregnancy and sexually transmitted infection (STI). Many women's advocates and policy-makers see the female condom as a new alternative that women can use to better protect themselves against HIV/STIs. However, program managers in health systems remain cautious about committing to wide-scale introduction of the method.

This subproject supports planning for and participation in the Global Consultation on the Female Condom. An important motivation for five FHI staff to participate in the GCFC is to get guidance on the CRTU research agenda by hearing the priority information needs of decision makers. Through this participation, FHI researchers will help guide interpretation of existing evidence, and receive guidance on what additional evidence is needed about the method.

The subproject will build on the female condom dissemination effort undertaken by FHI in 2000-2002 with support from USAID's Africa Bureau, which included an information needs assessment among African program planners, a research briefs series, sessions on the female condom at numerous technical conferences, and a broad campaign of electronic information dissemination. The September 2005 Consultation in Baltimore, which this subproject will use as a venue for results dissemination and partnership-building for in-country dissemination, offers an "opening" to inform commodities decisions, policymaking, and – indirectly – the information environment in which women in developing countries make method choice decisions.

The conference, and a limited number of research to practice to research follow-on activities, including a dissemination meeting in Madagascar where CTR research is being presented, will serve as a venue to disseminate current research on the female condom to program decision-makers to help them determine the appropriate role for the female condom in RH programs.

FY Workplan:
- FHI staff will prepare for and 5 FHI staff will participate in the Global Female Condom Summit in September 2005.
- In collaboration with PATH and other CAs, a communications strategy will be developed to promote use of reliable, authoritative information about the female condom among media, U.S.-based cooperating agencies, donors, and public health communities.

- Staff will update existing FHI research summaries on the female condom and share them globally with academics, researchers, program managers and providers, via printed briefs, and listserv and Web dissemination.
- Staff will work with partners such as the INFO Project and IPPF, that have strong channels of communication and entrée into service delivery or health training systems, as well as FHI's Research to Practice "champions" in order to enhance dissemination and utilization of findings discussed at the Summit.
- Partial costs of preparation, implementation, and participation of Theresa Hatzell in a local research dissemination workshop (Madagascar) directly relevant to Summit discussions will be supported.
- Information packets with updated female condom research summaries will be sent to 6,500 health professionals in developing countries in English, French, and Spanish.
- Updated materials will be posted on the FHI Web site, other Web sites, and listservs.

Evaluating the "Young Men as Equal Partners" Project

Status: To be approved

Projected End Date: March 30, 2008

Country(ies): Uganda and Kenya

FCO: 114100

Technical Monitor: S Thomsen

Subgrantee: TBD

Collaborating Agency(s): The Swedish Institute for Sexuality Education (RFSU)

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Approaches for overcoming male resistance to male condom use, informed in part by "exemplars" who succeed in using condoms more often than the norm, documented and replicated in three countries.

Subproject Objective(s): 1) To evaluate the effects of RFSU's Young Men as Equal Partners project on responsible sexual behavior (abstinence or condom use) of the young men who are targeted by the intervention; 2) to detect changes in young men's attitudes towards gender norms, through self- and clinic reports of STIs; 3) to detect changes in attitudes towards male sexuality and male sexuality education among the teachers and health care providers who have been trained; and 4) to observe for differences in attitudes, sexual behaviors and experiences with violence and unwanted pregnancies reported by young women in the subproject catchment area.

Description: Current efforts to slow the rapid spread of HIV/AIDS in Eastern and Southern Africa include heavy investments in educating youth on the dangers of HIV/AIDS through peer education, and school and health facility-based programs. However, despite frequent calls for more male involvement in such programs, little is known about how programs for young men should look, and what works best.

The Swedish Association for Sexuality Education (RFSU), in association with the Family Planning Associations of Kenya (FPAK) and Uganda (FPAU) are implementing a program entitled "Young Men as Equal Partners." The primary goal of the project is to sensitize, train and support young men aged 10-24 to act as role models in sexual and reproductive health and on gender issues within their community, and to advocate for male involvement in society at large. The project has three major modes of communication: young male peer educators, trained male schoolteachers, and trained service providers in sexual and reproductive health (SRH). The curriculum covers topics such as anatomy, fertility awareness, sexuality, safer sex, sexual abuse, relationships and gender roles. The target group of the intervention is young men aged 10-24 years. FHI, through the CRTU, will evaluate the effectiveness of the RFSU-supported intervention. The relationship between RFSU and FHI will be formalized with a memorandum of understanding (MOU).

The study will use pre/post-test design with control sites. Cross-sectional surveys of young men will take place at baseline, 12 months, and 18 months in order to determine the impact of the intervention. There will be 3 control and 3 intervention sites in each country. A baseline and 18-month follow-up of young women in all 6 sites will also be carried out. Providers and teachers will be surveyed before and after training on their attitudes towards male sexuality and services for men to detect the impact of the training curriculum. The study will include a process and cost evaluation. The results of this evaluation should provide guidance for the program planners and policymakers in East Africa on the effectiveness of male sexuality education on improving the sexual attitudes and behaviors of youth.

FY Workplan:

- The study protocol will be written and approved.
- Study sites will be visited by the technical monitor.
- Investigators will be identified in Kenya and Uganda.
- Subagreements will be established with investigators.
- Baseline data will be collected in 6 sites.
- Baseline data will be reported to collaborators.
- A cost analysis plan will be developed.
- A process evaluation plan will be developed.
- An analysis plan will be developed and approved.

Evaluating Strategies to Recruit Participants for "True Effectiveness" Trials of Barrier Methods in Contrasting Cultures

Status: To be approved **Projected End Date:** September 2007

Country(ies): Madagascar, U.S., and a CRTU emphasis country

FCO: TBD **Technical Monitor:** Larry Severy

Collaborating Agency(s): University of North Carolina and an institution in an emphasis country, to be identified.

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated.

Subproject Objective(s): To develop and test strategies to recruit women willing to participate in a one-month, placebo/no method-controlled contraceptive effectiveness trial. Two groups of women are of interest:

- women who actively desire pregnancy but who are willing to delay conception for one month
- women who are willing to accept pregnancy but are not necessarily actively trying to conceive

Description: We will develop and evaluate culturally appropriate recruitment strategies directed at these groups of women at the three study sites. These strategies will be guided by a host of interviews and focus groups with potential participants, community stakeholders and others in a position to convey information about the local culture. The interview design process will incorporate information derived from local health officials, FHI offices and USAID missions.

We will implement these strategies for a limited period of time and will interview women who respond to determine whether or not they would be willing to enroll in a trial, what aspects of the recruitment strategy and trial design they find acceptable and problematic, and what suggestions they have for improvement of the study approach. In addition, we will test an informed consent document with these same women, to ensure that it clearly conveys the goals and methods of the study, particularly the requirement that study participants must accept a risk of pregnancy during the trial.

We will amend our approach based on the data collected, in an iterative fashion. Ultimately, we hope to arrive at a recruitment method and trial design that is likely to yield acceptable enrollment and follow-up rates, which we can then use in the development of an actual trial.

FY Workplan:

- A protocol will be finalized and submitted for PHSC approval.
- Study instruments will be finalized.
- Sites and principal investigators will be identified.
- Subagreements will be finalized.
- Data collection will be initiated at one of the three sites.

Evaluating Disinhibition of Condom Use in a Diaphragm Trial

Old Title: Evaluating Disinhibition in a Diaphragm Trial

Status: To be approved **Projected End Date:** September 30, 2007

Country(ies): Madagascar

FCO: 112115 **Technical Monitor:** M Steiner

Subgrantee: TBD

Collaborating Agency(s): University of North Carolina (UNC)

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated.

Subproject Objective(s): To assess the potential of "condom migration" by comparing the proportion of participants with biological evidence of recent unprotected intercourse (i.e. PSA positive) at the screening visit, the enrollment visit and at least 3 follow-up visits.

Description: With any hierarchical approach to HIV/STI prevention, clients may substitute more effective methods with less effective methods (Miller 2004). In diaphragm studies to assess their effectiveness in preventing STI acquisition, researchers are concerned that condom use may decrease after participants have been enrolled due to a sense of protection offered by the diaphragm. Countering this concern, several studies suggest that, in fact, sexual risk-taking behavior decreases during trial participation (e.g. Bartholow et al, 2005). But such studies assess "condom migration" through self-reported measures, and self-reports of condom use are often inaccurate because of the social desirability to over-report condom use once enrolled into a trial.

In the Sexually Transmitted Infections Clinical Trials Group (STI-CTG) supported diaphragm trial in Madagascar under the direction of Dr. Frieda Behets (UNC), we proposed an ancillary study to collect vaginal swabs at screening, enrollment and at least 3 follow-up visits to test for PSA from a random sample of 400 participants. We will include a module of detailed questions to assess the number of coital acts and condom use during the previous two days.

The main objective is to assess the potential of "condom migration" by comparing the proportion of participants with biological evidence of recent unprotected intercourse (i.e. PSA positive) at the screening visit, the enrollment visit and at least 3 follow-up visits. If the proportion of participant specimens showing evidence of PSA remains constant from the screening visit to the end of the study, this would suggest that disinhibition is not a major concern. If the proportion showing evidence of PSA increases, this would suggest disinhibition in the trial through lower condom use and/or a higher coital frequency. If the proportion showing evidence of PSA decreases, this would suggest participants are engaging in safer sex by using more condoms and/or a lower coital frequency.

Data from our ancillary study will be combined with the qualitative data collected as part of the parent study looking at disinhibition and condom migration.

FY Workplan:
- The protocol will be finalized and submitted to PHSC for approval.
- Sub agreements and study instruments will be finalized.
- Data collection will be initiated.

Production Surveillance – Domestic Procurement - Condoms

Status: Ongoing **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 148100 **Technical Monitor:** S Hamel

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To ensure pre-distribution quality of condoms procured domestically by USAID for developing country programs.

Description: This program began in 1990 to provide close scrutiny of condom production and to ensure that condoms, procured domestically and distributed to developing countries by USAID, meet all performance standards. 100% of production lots are evaluated for acceptance prior to distribution, and factories are periodically inspected for adherence to GMPs and USAID contract requirements. This subproject tracks payments for contracted sampling services including sample reimbursements. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCOs 8015 Condom Production Surveillance and 8018 Production Surveillance Sampling).

FY Workplan:

- Monitoring of production activities will be performed as scheduled or as needed to meet USAID/CSL procurement objectives. 100% of production lots will be evaluated for acceptance prior to distribution.
- Results of audits and failure investigations, including recommendations for improvement, will be submitted to USAID/CSL.

Production Surveillance – Offshore Procurement - Condoms

Status: Ongoing **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 148101 **Technical Monitor:** E Carter

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To ensure pre-distribution quality of condoms procured offshore by USAID for developing country programs.

Description: This program, which began in 2005, provides close scrutiny of offshore condom production and ensures that condoms produced by contracted factories meet USAID procurement specifications prior to distribution to field programs. 100% of production lots are evaluated and factories are inspected periodically to ensure compliance with GMPs and USAID contract requirements. This subproject tracks payment for contracted sampling services and sample reimbursements. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCOs 8015 and 8018).

FY Workplan:

- Monitoring of production activities will be performed as scheduled or as needed to meet USAID/CSL procurement objectives. 100% of production lots will be evaluated for acceptance prior to distribution.
- Results of audits and failure investigations, including recommendations for improvement, will be submitted to USAID/CSL.

ACTIVITY DESCRIPTIONS FOR APPROVED MICROBICIDE FUNDED ACTIVITIES

This section of the CRTU Year 1 Workplan includes descriptions for activities already approved by USAID on the FY2005 Microbicide Accounting Funding Matrix. As a part of the Year 1 Workplan, we have chosen to simply resubmit those activity descriptions presented to USAID on February 11, 2005 in our Draft Microbicides Workplan submission. Please reference the CRTU Year 1 Workplan Budget for specifics on the budget allocations for these activities. Note: there are additional microbicide activities that FHI would like to do this year under the CRTU but currently no further microbicide funding is available. If funds are identified during the year, FHI will present each idea for preliminary approval.

Goals	Outcomes
I. To develop, evaluate and seek approval for microbicides with and without contraceptive effects	A. Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate. B. Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate. C. Five new sites for pivotal microbicide trials established, qualified, and functioning, with appropriate stakeholder involvement. D. Two new approaches for evaluating the safety or effectiveness of topical microbicides developed and validated. Results will be shared with other research organizations, funding agencies, and other interested parties. E. Two new approaches for evaluating the safety or effectiveness of topical microbicides developed and validated. Results will be shared with other research organizations, funding agencies, and other interested parties. F. Two new delivery systems/methods of administration for topical microbicides evaluated. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate. G. One pivotal trial comparing oral versus topical microbicides implemented. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate. H. Innovative strategies to increase retention and reduce product interruptions in trials developed and tested. I. To obtain information needed to help interpret clinical trial results and to improve the design and implementation of future trials, social and behavioral studies will be conducted on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies.
II. To inform microbicide introduction by research and information dissemination	A. Acceptability of at least three different formulations or microbicide delivery systems assessed in at least three regions. B. In collaboration with various stakeholders (potential users, providers, women's groups, ministries of health, and service delivery programs), a plan to determine appropriate population and service delivery targets for the introduction of the first available microbicides developed. C. Acceptability and feasibility of integrating microbicides into STI and VCT clinics and

Goals	Outcomes
	other services used by individuals at high risk for HIV acquisition evaluated. D. Messages and materials for microbicides in various service delivery settings developed and evaluated. E. The impact of microbicide introduction and use (contraceptive and non-contraceptive) on family planning use and pregnancy evaluated. F. Clients' willingness to pay for microbicides assessed. G. At least one pre-introductory study of effectiveness, extended safety and acceptability conducted while product regulatory approval is pending. Results will support local approvals and help further guide product introduction once approval is obtained. H. Programmatic and biomedical lessons learned from research synthesized, and results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, scientific advisory committees, USAID, clients, and others for incorporation into practice and procurement decisions.
III. To introduce safe and effective microbicides and enhance correct and consistent use by populations with greatest need	A. Product quality assurance methodologies for testing and analyzing candidate microbicides further refined and applied. B. Impact of different strategies for microbicide provision among the first target population assessed as products become available (i.e., actual use studies).

Note: The first subproject in this section, "Safety and Feasibility of the Diaphragm Used with Acidform Gel," was <u>not</u> part of the FY 2005 Microbicide Funding Matrix. Although previously funded with microbicides monies, it will be funded in 2005-2006 with core funds.

Safety & Feasibility of the Diaphragm Used with ACIDFORM Gel or KY® Jelly

Status: Ongoing

Projected End Date: June 30, 2006

Country(ies): South Africa

FCO:
Clinical: 112103 (previously 2276)
Behavioral: 116101

Technical Monitor:
Clinical: S. Wevill
Behavioral: G. Guest

Collaborating Agency(s):
Clinical: CONRAD
Behavioral: CONRAD and Progressus (South Africa)

USAID Intermediate Objective to be addressed
IR2= Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed:
- Evidence-based strategies to increase use of barrier methods for contraception by couples with at least one HIV+ partner developed, evaluated and implemented
- Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates will be determined. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.
- Two new delivery systems/methods of administration for topical microbicides will be evaluated. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.
- At least one promising new diaphragm evaluated for contraceptive effectiveness and/or prevention of STI.

Subproject Objective(s):
Clinical: To provide statistical, data management, behavioral analysis, and monitoring support for a CONRAD study to assess the effect of a diaphragm used with ACIDFORM (vs. one used with KY Jelly) on symptoms and signs of irritation of the external genitalia, vagina, and cervix; 2) evaluate the willingness of women to use the diaphragm with a gel prior to each vaginal sexual act for a period of 6 months; and 3) compare the differences in vaginal health following 6 months use of a diaphragm with ACIDFORM vs. one used with KY Jelly.

Behavioral: 1) To determine if/how study participants group together based on psychological and behavioral factors; 2) to describe and measure participants' subjective experiences using product, at baseline (Month 1) and over the course of the trial (Months 1, 3, 5, 6); 3) to describe and measure participants' use of gel and diaphragm during vaginal sex, at baseline (Month 1) and over the course of the trial (Months 1, 3, 5, 6); and 4) to measure the relationship between subjective experience with product and reported usage, at baseline (Month 1) and over time.

Description:
Clinical
ACIDFORM gel was developed with the principle that an acid-buffering vaginal formulation that maintains the vaginal pH below 5.0 when the ejaculate is introduced in the vagina or when a vaginal infection is present would be both an ideal contraceptive and anti-microbial agent. Based on pre-clinical and clinical data, ACIDFORM gel appears to be a promising candidate spermicide and microbicide, with an excellent safety profile justifying further development and evaluation.

This CONRAD study is a placebo-controlled, randomized, triple-masked study which as enrolled 120 sexually active women at low risk for HIV infection. Participants were instructed to insert a diaphragm and apply either ACIDFORM or KY Jelly prior to having vaginal intercourse, and leave the diaphragm in the vagina for a minimum of 8 and a maximum of 24 hours after intercourse. If they have multiple sexual acts during this period, they were instructed to apply a new dose of vaginal gel with each act. Participants were enrolled for a study period of six months.

Following use of the assigned product, the assessment of signs and symptoms of irritation of external genitalia, vagina and cervix will be conducted involving a review of disruption of the epithelium and blood vessels as seen on colposcopy. Differences in vaginal health will be assessed using results of wet mounts, pH, gram stains and cervical-vaginal lavages for cytokines.

Behavioral

One of the primary objectives for the Acidform study is "to assess the participants' willingness and ability to use the diaphragm with a gel applied prior to each vaginal sexual act for a period of six months". The purpose of the behavioral analysis is to address several important questions regarding feasibility of women consistently using the gel and diaphragm.

One of the objectives of the behavioral analysis plan is to map experience with, and use of, the product over the course of the trial. Product usage by demographic and behavioral factors will also be documented as will trends in some of the details surrounding product usage. The behavioral analysis will descriptively map ease of use and comfort levels associated with product use over time to see if observed trends are related to the primary acceptability measures of overall experience and product use.

Growth Curve Analysis (GCA) will be the primary method to assess changes in acceptability by participants over time, and the relationship of these changes to both time-invariant variables (e.g., education, age) and time-varying variables (e.g., frequency of sex in past 7 days). GCA will be complemented by other statistical analyses and qualitative data analysis where appropriate.

NOTE: In July 2005, $28,600 of CTR core funds was added to the behavioral portion of this microbicides activity to facilitate subproject continuation prior to the initiation of CRTU core fund disbursement. FHI is providing biostatistical, data management, monitoring and behavioral analysis support to this study.

FY Workplan:

Clinical:

- The in-country monitor will continue to conduct regular monthly monitoring visits and will send in completed CRFs after each visit until participant follow-up has concluded. Participant follow-up is expected to end in late November 2005.
- The FHI monitor will conduct a close out visit in January 2006.
- All data will be entered, and all queries will be resolved.
- All medical and in-house coding will be completed, and the database will be frozen.
- The study table shells will be developed.
- FHI will review CONRAD's final report as requested.
- Study documentation will be archived.

Behavioral:

- Staff will conduct analysis on behavioral data.
- Staff will write 1-2 manuscripts based on the results.
- Staff will disseminate findings to appropriate organizations.

Randomized Controlled Trial of Cellulose Sulphate (CS) Gel and HIV in Nigeria

FCO/Activity Number: 2266 **Technical Monitor:** Vera Grigorieva

Primary Country of Activity: Nigeria

CRTU Strategy Outcome to be addressed:

- Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Implementers: Health Matters Inc, Lagos Nigeria; Institute of Tropical Medicine, Antwerp, Belgium; Lagos University Teaching Hospital, College of Medicine, Lagos, Nigeria; STOPAIDS Organization, Port Harcourt, Nigeria; University of Port Harcourt Teaching Hospital, Port Harcourt, Nigeria
Period: Approved 9/7/2001; anticipated end date 6/30/2008

Objectives:
1) To determine the effectiveness of CS gel in preventing male-to-female vaginal transmission of HIV infection among women at high risk; 2) to determine the effectiveness of CS gel in preventing male-to-female transmission of gonorrhea and chlamydial infection among women at high risk.

Description: The search for an effective vaginal microbicide remains urgent, given the continuing HIV epidemic. This is especially true in sub-Saharan Africa which bears a disproportionate burden of HIV/AIDS cases. Cellulose sulfate (CS) gel is a promising microbicide candidate. CONRAD (maker of CS gel) is the sponsor of this study and will supply the study product for this Phase III study.

This is a randomized controlled trial of 2,160 women, aged 18-35 at high risk for HIV, who will be followed for one year of study participation. Half the women will use CS gel, and half will use a placebo gel. Combined incidence rate of HIV-1 and HIV-2 infection will be compared between the two groups to evaluate the effectiveness of CS gel. Also, incidence rates of gonorrhea and chlamydial infection will be similarly compared. Results from this study may help women worldwide, should the gel prove to be an effective HIV-prevention method. All women who consent to be in the study will be counseled on condom use.

This subproject is supported by USAID funds earmarked for microbicide research.

FY Workplan:

- Site monitoring trips will take place at both sites on a quarterly basis or as deemed necessary by the Project Leader.
- Enrollment is anticipated to be completed by December of 2005.
- A PHSC visit to Nigerian sites is schedule for summer of 2005.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 - "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

Nigeria SAVVY Phase III RCT

FCO Number: 2277 **Technical Monitor:** Paul Feldblum

Primary Country of Activity: Nigeria

Collaborating Agencies, Implementing Sites or Subcontractors: Health Matters, Lagos, Nigeria; Nigerian Institute of Medical Research, Lagos, Nigeria; University College Hospital, University of Ibadan, Ibadan, Nigeria; Biosyn (Sub-contractor)

Period: 8/2002 – 8/2007

CRTU Strategy Outcome to be addressed:

- Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Objective: To assess the effectiveness of SAVVY vaginal gel in preventing HIV among Nigerian women at high risk. NB: At the request of the sponsor (Biosyn, Inc.), the previously reported secondary endpoint, to determine SAVVY's effectiveness in preventing male-to-female transmission of gonorrhea and chlamydial infection among women at high risk, has been dropped.

Description: This is a Phase III placebo-controlled, randomized, triple-masked study. A total of 2,142 uninfected women, aged 18-35 at high risk for acquiring HIV, will be recruited over 12 months at study sites in Ibadan and Lagos, Nigeria. Women who consent to be in this study will be randomized into either a condom/SAVVY or condom/placebo group and will be followed for 12 months. After completion of the study, incidence rates of HIV-1 and HIV-2 infection will be compared between the two groups. This subproject is supported by USAID funding earmarked for microbicide research. Biosyn, Inc. is the maker of SAVVY. They will supply the SAVVY and placebo gels for the study. NB: After negotiations with the USFDA and deciding on a final study design, the Sponsor requested 12 months of follow-up time for each study participant and to drop gonorrhea and chlamydia as secondary endpoints. FHI amended the protocol to reflect this new study design and obtained all necessary approvals.

Proposed Workplan: Continue and complete screening and enrollment in the trial. Begin follow-up in the trial. Monitor study progress and procedures and participant safety on a regular basis. Submit annual safety report to Biosyn in December 2005. Prepare for statistical report and clinical study report.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 - "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

Ghana SAVVY Phase III RCT

FCO Number: 2278 **Technical Monitor:** Leigh Peterson

Primary Country of Activity: Ghana

Collaborating Agencies, Implementing Sites or Subcontractors: Komfo Anyoke Teaching Hospital (KATH); Noguchi Memorial Institute for Medical Research (NMIMR); Virtual Access (VA); Biosyn (sub-contractor)

Period: 8/2002 – 8/2007

CRTU Strategy Outcome to be addressed:

- Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Objective: To assess the effectiveness of SAVVY vaginal gel in preventing HIV among Ghanian women at high risk. NOTE: At the request of the sponsor, the previously reported secondary endpoint (to determine Savvy's effectiveness in preventing male-to-female transmission of gonorrhea and chlamydial infection among women at high risk) has been dropped.

Description: This is a Phase III placebo-controlled, randomized, triple-masked study. A total of 2,142 uninfected women, aged 18-35 at high risk for acquiring HIV, will be recruited over 12 months at study sites in Accra and Kumasi, Ghana. Women who consent to be in this study will be randomized into either a condom/SAVVY or condom/placebo group and will be followed for 12 months. After completion of the study, incidence rates of HIV-1 and HIV-2 infection will be compared between the two groups. This subproject is supported by USAID funding earmarked for microbicide research. Biosyn, Inc. is the maker of SAVVY. They will supply the SAVVY and placebo gels for the study. NOTE: After negotiations with the USFDA and deciding on a final study design, the Sponsor requested 12 months of follow-up time for each study participant and to drop Gonorrhea and Chlamydia as secondary endpoints. FHI amended the protocol to reflect this study design and obtained all necessary approvals.

Proposed Workplan:

- Participant recruitment and follow up will continue.
- Quarterly monitoring visits will continue.

Involvement of Other Donors and Interested Parties: This clinical trial is being funded by USAID. Product is being supplied by Biosyn (who has used USAID funds through CONRAD to manufacture supplies). Biosyn holds the IND.

Independent Monitoring of CONRAD Collaborative Studies

FCO Number: 2285 **Technical Monitor:** Ginger Pittman

Primary Country of Activity: Worldwide

Implementing Sites: Langata Health Facility, Nairobi, Kenya; Spilhaus Clinic, Belgravia, Harare. NOTE: Subagreements with these sites are funded by CONRAD.

Period: Oct 2003 through Dec 2005

CRTU Strategy Outcome to be addressed:

- Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate
- Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective: To provide clinical monitoring services to CONRAD specifically for those studies funded by USAID.

Description: This subproject is funded by USAID funds for microbicide research and serves to provide financial support for FHI's clinical monitoring costs related to CONRAD studies. When monitoring services in addition to statistical and/or data management support services are provided, then monitoring costs are charged directly to the study assigned FCO.

Proposed Workplan: Sites will be monitored according to study needs as determined by CONRAD.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 - "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

Statistical Methods for Microbicides Research

CA Activity Number: FCO 9113 **Technical Monitor:** Douglas Taylor

Primary Country of Activity: USA

Implementers: Family Health International

Period: November 2000 to June 2005

CRTU Strategy Outcome to be addressed:

- Two new approaches for evaluating the safety or effectiveness of topical microbicides developed and validated. Results will be shared with other research organizations, funding agencies, and other interested parties.

Objective: 1) To review statistical methods needed to answer questions concerning the effectiveness of microbicides in preventing HIV/STI transmission; 2) to conduct research on such methods; and 3) to develop recommendations for study design and analysis.

Description: Randomized trials designed to evaluate the effectiveness of microbicides in preventing HIV/STI transmission pose a number of statistical challenges. These include, but are not limited to: choice of an appropriate control, heterogeneity of randomized participants, interval censoring of outcomes, and competing risks due to co-infections. The relevant statistical literature will be reviewed in order to help address these concerns. Data from previous studies (e.g., the Cameroon N-9 film and Conceptrol gel studies) will be used to motivate the selection of appropriate statistical models for analysis of randomized microbicide effectiveness trials, and to develop recommendations for the design and analysis of future studies.

Proposed Workplan:

- Relevant analysis methods will be applied to previous FHI effectiveness study data. Limitations of existing methods will be identified, and research on new solutions will continue. In particular, design challenges for 'second generation' microbicide trials will be explored.
- A summary of findings will be presented to FHI researchers as they are obtained. Selected results will be further disseminated at scientific meetings and in the statistical and clinical research methodology literature.
- FHI biostatisticians will carry out preparatory work for their interim analysis of the Population Council's Phase III effectiveness trial. (*Support for implementation of the planned interim analysis is being requested as the Carraguard Phase III Trial.)*
- Continue to provide input as requested by USAID or the Alliance for Microbicides on key design, analysis and interpretation issues that arise for microbicide trials.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 – "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

Involvement of Other Donors and Interested Parties: Alliance for Microbicides, Population Council

Phase I Study of the BufferGel Duet's Functional Performance, Safety and Acceptability

FCO Number: 2292 (formerly 9117) **Technical Monitor:** Ginger Pittman

Primary Country of Activity: USA, Dominican Republic

Implementing Sites: (1) Eastern Virginia Medical School, Norfolk, VA; (2) PROFAMILIA, Santa Domingo, DR. NOTE: Subagreements with these sites are funded by CONRAD.

Period: Oct 2001 through Dec 2005

CRTU Strategy Outcome to be addressed:

- Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective: To provide statistical and data management support to a CONRAD study designed to assess the function, safety, effect on vaginal pH, and acceptability of the BufferGel Duet.

Description: The BufferGel Duet (formerly called the BufferGel Cup) is a single-use disposable contraceptive intravaginal device made of clear polyurethane and preloaded on both its cervical and vaginal sides with BufferGel, a nondetergent spermicidal microbicide. The focus of this clinical study is on the functional performance of the device (ease of insertion and removal, correctness of position after insertion, and frequency of dislodgments), but safety, effect on vaginal pH and acceptability will also be assessed. A total of 30 couples, healthy and not at risk for pregnancy, will be enrolled at two sites and will use the device for one week.

NOTE: FHI is providing data management and statistical analysis support to this study, funded by USAID monies designated for microbicide development.

Proposed Workplan: FHI's Data Management staff will prepare record lay-outs and data error check specifications, as well as program and test data entry screens and data error checks. Study data will be entered into the Clintrial system as it arrives from the sites, and queries will be generated and processed. FHI's Biostatistics staff will develop detailed table shells for data analysis and begin drafting data analysis programs. The planned analyses will be conducted and the statistical report prepared and sent to CONRAD.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 – "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

Sustained Acceptability of Vaginal Microbicides: Male and Female Perspectives

FCO Number: 9386 **Technical Monitor:** Betsy Tolley

Primary Country of Activity: India

Collaborating Agency: National AIDS Research Institute (NARI)

Period: 10/16/2001- 6/30/2007

CRTU Strategy Outcome to be addressed:
Innovative strategies to increase retention and reduce product interruptions in trials developed and tested.

CRTU Strategy Outcomes to be addressed:
Social and behavioral components and/or ancillary studies within microbicide clinical trials conducted to provide information on: sexual relationships and practices; the social and cultural context for microbicides; potential for covert use; and community support and policies.

Objective: 1) To identify and describe factors that enable individuals and couples to use microbicides consistently and long-term; and 2) to account for the effects of clinical trial and acceptability research participation on microbicide use, including motivations for joining the trial; the importance of counseling and support provided by clinical trial staff in maintaining product use; and the importance of interactions with acceptability research staff in maintaining product use.

Activity Description (Please include background, policy and programmatic implications and basic study design information.): The Sustained Acceptability study will integrate qualitative and quantitative data collection methods in a longitudinal study of microbicide acceptability in Pune, India. It will do so by building on to Phase I (FCO 433) and Phase 2b (FCO 735) microbicide clinical trials research funded by NIAID and implemented under the auspices of the HIV Prevention Trials Network (HPTN). A pilot study, conducted during the Phase I clinical trial, will include semi-structured in-depth interviews with individuals and couples who exhibit different patterns of microbicide and condom use. Interviews will focus on key concepts believed to influence risk-reduction behaviors including: HIV risk perception, self efficacy, couple harmony, and sexual communication. Information collected during the pilot study will be used to refine data collection instruments to be used in a longitudinal assessment of acceptability.

It is projected that a total of 410 women will be enrolled in the HPTN Phase 2b (FCO 735) parent study over a recruitment period of 17 months and followed up for a minimum of 18 months. These women and their primary partners, if the woman agrees to partner contact, will be recruited into the parallel acceptability study. These participants will provide two sets of data: core acceptability data developed for the clinical trial and enhanced acceptability data. The enhanced questionnaires will measure individual and couple scores on key psychosocial factors believed to mediate microbicide or condom use, as well as motivations for clinical trial participation. In addition, clinical trial providers and a small sample of women and willing partners will also be interviewed in-depth, using a more flexible and open format.

Proposed Workplan:
- The quantitative data will be factor analyzed and a final questionnaire drafted for use in the longitudinal study.
- A second paper on the scale development phase of the subproject will be drafted for publication in peer-reviewed journals.
- The longitudinal acceptability study will be initiated.
- Some additional behavioral and social science research may be conducted in support of the microbicide clinical trial on which the longitudinal acceptability study will piggyback.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 - "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

HPV Add-on to Randomized Controlled Trial of Cellulose Sulphate (CS) Gel

FCO Number: 2298 **Technical Monitor:** Kavita Nanda

Primary Country of Activity: Nigeria

Collaborating Agencies, Implementing Sites or Subcontractors: CONRAD

Period: 4/2004 – 8/2006

CRTU Strategy Outcome to be addressed:

- Two new approaches for evaluating the safety or effectiveness of topical microbicides developed and validated.

Objective: 1) To evaluate the effect of CS on the incidence of HPV infection; 2) To evaluate the effect of CS on persistence of HPV infection.

Description: Genital human papillomavirus (HPV) infections cause over 99% of squamous-cell cervical cancer. Cellulose Sulfate (CS) was recently shown to strongly inhibit HPV in vitro. This add-on study presents a unique opportunity to understand the potential role of CS on HPV infection among women. If CS can be shown to prevent HPV, it will be a useful tool in the battle against cervical cancer. Because it is an add-on to an existing study, the add-on study can be conducted relatively inexpensively and quickly. The primary study is a randomized controlled trial of 2,160 women, aged 18-35 at high risk for HIV, who will be followed for one year of study participation. Half the women will use CS gel, and half will use a placebo gel. We plan to begin the HPV add-on study approximately 3 months after the main study begins, and hope to enroll 2000 women.

Proposed Workplan:

- Conduct preliminary tests to ensure that gels do not inhibit the HPV PCR assay
- Finalize the protocol, and obtain IRB and PHSC approval
- Finalize site budgets and subagreements
- Begin enrolling participants

Contribution to USAID Results Framework: This add-on study will contribute towards USAID's Strategic Support Objective #5: Increased Use of Effective Interventions to Reduce the Threat of Infectious Diseases of Major Public Health Importance.

Involvement of Other Donors and Interested Parties: Because cellulose sulfate (CS) is a CONRAD product, they will be interested in the results of this study.

Preparedness for CONRAD Phase III Trial of CS

FCO Number: 9517 **Technical Monitor:** Larry Severy

Primary Country of Activity: Multiple Countries

Collaborating Agencies, Implementing Sites or Subcontractors: CONRAD

Period: December 6, 2004 – December 31, 2005

CRTU Strategy Outcome to be addressed:

- Innovative strategies to increase retention and reduce product interruptions in trials developed and tested.
- Innovative strategies to increase retention and reduce product interruptions in trials developed and tested.

Objective: To improve the quality and the operations for the CS clinical trial by developing empirically grounded strategies to: 1) increase participant recruitment and retention, a task that has proved difficult in previous HIV clinical research, especially among high risk populations; 2) improve adherence to study protocol, including product use and attending regularly scheduled clinic visits; and 3) implement a comprehensive informed consent process designed to increase participants' understanding of informed consent.

Description: CONRAD has requested a partnership with FHI/BASS to conduct preparedness activities for their proposed Phase III Clinical trial to test the effectiveness of cellulous sulfate (CS) as a microbicidal agent to prevent HIV among high-risk women (women with multiple partners). The trial is scheduled to begin in the second quarter of 2005 and continue for two years. Planned sites include India, Benin, Burkina Faso, Uganda, and South Africa. Initially the preparedness work in support of the CONRAD Phase III Trial of CS was included under FCO 1789 which was closed on 8/31/2004. The preparedness work was then included under FCO 2294, which also included all FHI work in support of the CONRAD Phase III Trial of CS: BIOS, Data Management, BASS and Clinical Monitoring. In December it was decided the project would be easier to manage if the preparedness work was given a separate FCO. All preparedness activities are now under the new FCO 9517.

Proposed Workplan:

- Betsy Tolley will travel to Bangalore, India to meet with the clinical trial team and develop and assess preparedness and BSS monitoring plans.
- A sub-agreement with ICHAP in Bangalore, India will be negotiated for the preparedness and BSS monitoring.
- Betsy Tolley and the site behavioral team will conduct clinical trial training in recruitment/retention and the informed consent process in Bangalore, India.
- Monitoring trips will be made to all sites.
- Behavioral teams will work with the clinical trial on an ongoing basis to: determine local community attitudes about the trial, and develop strategies to improve community support of the trial; troubleshoot problems that may occur during recruitment/retention and when necessary conduct interviews with participants at risk for dropping out of the clinical trial; and provide ongoing technical assistance throughout the course of the clinical trial.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 - "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

Evaluation of a Novel Low-cost Vaginal Drug Delivery Device

FCO Number: 132103 **Technical Monitor:** David Sokal

Primary Country of Activity: USA

Collaborating Agency, Implementing Site and/or Subcontractors:

Period: June 2004 through August 2006

CRTU Strategy Outcome to be addressed:
- Two new delivery systems/methods of administration for topical Microbicides evaluated.

Objective: 1) To develop hand-made prototypes of a new vaginal delivery device for microbicides or other vaginal preparations; and 2) to assess acceptability of the device via focus group discussions or in-depth interviews.

Description: Current vaginal applicators are designed to deliver a prescribed amount of drug or lubricant. Though inexpensive, these applicators do not always deliver effective drug doses. Efficacious drug delivery is dependent on three factors: (1) delivery of the drug into the vagina; (2) spread of that drug throughout the vaginal vault; and (3) retention of the drug in the vagina. Consequently, efficacy and user satisfaction may be compromised by human error that results in leakage and/or inadequate coverage/spread of the drug. The proposed device was intended to employ an applicator technology that had not previously been used for vaginal microbicides, and placement, retention and leakage were intended to be minimized through the use of a non-woven material. It was believed that this device would release microbicide evenly, retain drug within the vagina for longer periods of time, and possibly allow for multiple sexual acts without re-dosing. Its unique design would possibly provide a degree of physical barrier protection as well. Under this subproject, a new vaginal delivery device for microbicides or other vaginal preparations was to be prepared. Focus group discussions or in-depth interviews regarding prototype acceptability were planned. Meanwhile a review of relevant patents was planned, and a patent application for the new device was to be prepared.

Proposed Workplan:
- Staff will complete work on a patent for the improved device.
- Based on qualitative comments from the CONRAD lime-juice study, work on design improvements to our new prototype will be completed.
- Staff will conduct some preliminary in-vitro evaluation work of the new prototypes at FHI's PQC lab.
- Staff will continue exploring additional sources of funding.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 – "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

Carraguard Phase III Trial: Interim Analysis for Data Safety and Monitoring Board

FCO Number: 139100 **Technical Monitor:** Rosalie Dominik

Primary Country of Activity: USA

Collaborating Agency, Implementing Site and/or Subcontractors: Population Council

Period: March 2005 (preparatory activities will be charged to FCO 9113) through June 2006

CRTU Strategy Outcome to be addressed:

- Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Objective: To provide interim analysis assistance, reporting and consultation for the Carraguard Phase III HIV effectiveness trial

Activity Description (Please include background, policy and programmatic implications and basic study design information.): In response to the urgent need for widely available and easy-to-use protection against the sexual transmission of Human Immunodeficiency Virus (HIV), Population Council Investigators have developed a topical microbicide called Carraguard® (PC-515). With USAID and Gates Foundation funding, they are in the process of implementing the Phase III Study of the Efficacy and Safety of the Microbicide Carraguard® in Preventing HIV Seroconversion in Women. The *primary objective* is to determine *the efficacy* of Carraguard® gel against HIV when applied vaginally prior to sexual intercourse. A Data Safety and Monitoring Board (DSMB) will preside over at least 2 interim analyses for the main study. In order to ensure that the Population Council's biostatistician remains blinded to the interim analysis results, they have requested that an FHI biostatistician implement the planned interim analyses, present the analysis to the DSMB and assist with additional interim analysis requests as needed.

Proposed Workplan:

- FHI biostatistics and data management staff will review and become familiar with key study documents (e.g., analysis plans, protocol and data collection forms), receive and secure interim datasets, perform interim analyses using analysis programs provided by the Population Council, distribute the confidential reports to the DSMB members, attend DSMB meetings (assumed one in South Africa and one in New York City), help the DSMB interpret results and perform additional analyses if requested by the DSMB. We expect at least two full interim analyses will occur during this time period.

Contribution to USAID Results Framework: This activity contributes to Strategic Objective 4 – "Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic."

Involvement of Other Donors and Interested Parties: Gates Foundation is co-funding the Population Council study.

Cross-Cutting Activities

A number of CRTU activities support and facilitate implementation of the subprojects encompassed in all of the technical strategies, and help to ensure that a primary goal of the CRTU is met: to facilitate the translation of research results into practice in the country programs supported by USAID. The 'crosscutting' activities included in this section of the Workplan are grouped into five categories: 1) Research Utilization; 2) Enhanced Country Programs; 3) Technical Leadership/Research Synthesis; 4) Product Quality and Compliance; and 5) Monitoring and Evaluation.

The Research Utilization category includes activities that focus on facilitating the participation and input of partners, both US- and field-based. Subprojects in this category support the process of obtaining input from MOU partners and others in setting the CRTU research agenda. They also foster collaborative efforts, including joint program efforts and the sharing of research results to contribute to best practices and enhance the quality of service programs. Important components include the Research-to-Practice (RtoP) leadership, as well as leadership for the timely and effective dissemination of research results. While RtoP and dissemination are also integrated into activities to be implemented under the technical strategies, the allocation of core resources for broader, crosscutting Workplan activities helps to maintain a focus and ensure the overall coordination of CRTU subprojects to meet this goal.

Enhanced country programs are another important emphasis in the CRTU, and resources are allocated to the assessment, selection, planning and support to maximize the impact of CRTU activities in improving reproductive health in a few countries. These countries will generally be the first choice for locating activities proposed under the technical strategies. In addition, we expect that the core resources invested in capacity development, research implementation, and research utilization activities in these countries will secure additional support from country missions, partner cooperating agencies, as well as local governmental and non-governmental agencies to scale up results of CRTU research and technical assistance. Where field support or other mission-provided funds augment the core funds for local capacity development and research activities that fall outside of the technical strategies, these activities are also included in this subsection.

As a primarily core-funded research agreement, the CRTU is also charged with providing broad technical leadership for USAID, its overseas missions and other cooperating agencies in the areas of contraceptive technology, microbicides, and reproductive health research. To this end, it is important to maintain core resources to represent all of the CRTU programs at key meetings, to synthesize results within and across all strategy groups, to be able to respond to emerging needs and requests from USAID, and to continue to facilitate the creative and collaborative vision for developing the activities that will enable FHI to meet the goals and expected outcomes through subsequent Workplans.

A number of the subprojects carried out by FHI's Product Quality Control (PQC) division also are broader than any one of strategies. Descriptions of these crosscutting and support activities are also included in this Workplan section.

Finally, FHI is committed to a strong Monitoring and Evaluation effort that addresses all components of the CRTU program. A subproject that supports the M&E effort for the CRTU is, therefore, included in this cross-cutting section.

Cross-Cutting
Research Utilization

Research to Practice Leadership

Status: To be approved **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 113114 **Technical Monitor:** E McGinn

Collaborating Agency(s): EngenderHealth, ADRA, Save the Children, MSH, JHU/INFO, WHO, Population Council, PATH, CONRAD, various in-country partners (Missions, MoH), and others TBD.

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:

- Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births.
- Evidence-based programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.
- Results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and other interested parties for incorporation into practice and procurement decisions.
- Policies and service delivery guidelines will be changed in at least one country to reflect new research findings.
- Evidence-based counseling approaches for male and female condom promotion incorporated into family planning service guidelines, including those used by HIV/AIDS programs (VCT, ART, PMTCT) in up to six countries.

Subproject Objective(s): 1) Internal technical assistance & capacity building for research utilization; 2) identification of RtoP priority topics and strategies; and 3) develop, maintain and implement memorandums of understanding (MoU) with key partners.

Description: Public health research is not an end in itself; rather, it is intended to improve service delivery, policies, and practices. Yet the gap between existing evidence and clinical and programmatic practice is substantial, with policy and practice changes often lagging well behind the evidence, despite substantial investments in research.

Under the CTR, FHI undertook the Research to Practice Initiative (RtoP) as a concerted effort to reduce this gap by establishing more effective links between researchers and service delivery organizations to both promote new and under-used research findings, and identify research questions that would address current issues in service delivery.

Under the CRTU project, this RtoP Leadership subproject will support the strengthening of capacity to promote research utilization and serve as the principal vehicle for developing, maintaining and implementing a network of Global MOU partnerships. MoU partnerships will help inform FHI's research priority setting process to ensure that future research addresses current service delivery needs. In

addition, strong partnerships will facilitate adoption of research findings and thereby enhance impact on policies and programs.

FY Workplan:
Further institutionalization of "Research to Practice" and "Practice to Research" approaches to FHI's work, will be achieved through:

- Development of a researcher tool (on-line and checklist format) to facilitate research utilization;
- at least one internal workshop/brownbag to orient staff on Research Utilization processes at FHI;
- development of an orientation package or process for new staff on Research Utilization; and
- continued TA and input into FHI's CRTU Research Priority Setting process to facilitate MoU partner and stakeholder input into FHI's research agenda.

Message development and promotion strategies will be achieved through:

- Development of at least one RtoP topical strategy for implementation during FY 06 -07;
- continued synthesis and dissemination of under-used research findings (UURF); and
- development, in collaboration with Information Programs, of two to four RtoP topical briefs.

RtoP technical assistance will include:

- TA to FHI staff to incorporate RtoP in concept proposals, protocols, and utilization strategies;
- TA to the Enhanced Country Program and other country partners on evidence-based practices (e.g., technical review of policies, stakeholder meetings) where funding permits; and
- institutionalization of a process for internal communication and coordination of MoU activities with various CA/PVO partners, including establishing a point person for each MoU partner.

Maintenance and implementation of MoUs with key partners will be achieved by:

- Establishing a system to ensure MoU partners' ongoing/regular input into FHI's workplans and vice versa;
- implementing at least two joint activities with MoU and other partners (separate approval and funding will be needed for specific method-related strategy sub-projects, even though they are negotiated under this sub-project;
- providing outreach to and engagement of PVO community and other non-traditional partners (e.g., NGOs based in Africa), including identification of at least one other CA/PVO with whom FHI would like to seek an MoU; and
- continuing documentation of research utilization by at least two CAs/PVOs.

CTR End-of-Project & CRTU Project Launch Meeting

Status: To be approved **Projected End Date:** October 31, 2005

Country(ies): Washington, DC

FCO: 113120 **Technical Monitor:** T Oronoz

Subgrantee: N/A

Collaborating Agency(s): N/A

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: This meeting addresses the dissemination outcomes inherent in each strategy and for the CRTU overall. It is also intended to foster collaboration with partners.

Subproject Objective(s): 1) To disseminate the key findings of the CTR; 2) to encourage other USAID-supported programs, service delivery CAs and PVOs to pick up and adopt the lessons learned; and 3) to further the goals of coordination and collaboration under the CRTU.

Description: The main purpose of this meeting is to showcase CTR results and lessons learned so that others can apply them. In looking forward to the new CRTU, this meeting should also foster the identification of opportunities whereby other CAs or PVOs, working independently or in partnership with FHI, can chose to scale up or replicate some of the key results of the CTR, as well as to partner on new efforts.

FHI is planning a one-day meeting on October 18, 2005 Washington, DC to discuss CTR accomplishments and describe the major strategic goals and outcomes for the new CRTU. The agenda will include welcome remarks, a summary of the CTR, and an overview of the CRTU in the morning, with breakout sessions for MoU partners in the afternoon. Approximately 250-300 people from USAID, CAs, PVOs and other donors will be invited to attend the morning meeting. We expect about 100 people to participate. A smaller, selected group will be invited to attend the afternoon breakout sessions; these participants will receive a separate email with details regarding the work to be done in their sessions concerning collaboration with the FHI.

FY Workplan:
- The agenda will be determined and speakers appointed.
- Invitations will be sent by email. The USAID Technical Advisor will issue the “Save the Date” notice to USAID GH/POP. FHI will email it to cooperating agencies and others.
- All logistical arrangements will be made with the Ronald Reagan conference services staff.
- Materials will be assembled.
- The meeting will be held in Washington, DC on October 18, 2005.
- A separate afternoon session with MoU partners will advance Workplan collaboration for 2006-2007.

Network of Champions

Old Title: Network of Champions: Supporting the Enhanced Country Program

Status: To be approved

Projected End Date: June 30, 2007

Country(ies): 2-4 Countries TBD

FCO: 113113

Technical Monitor: E McGinn

Subgrantee: N/A

Collaborating Agency(s): N/A

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting subproject, the outcomes the Network of Champions will address cut across strategies. Broadly they pertain to advocacy for policy change; incorporation of evidence-based approaches into international recommendations, country-specific guidelines, and program documents; provision of technical assistance; testing and application of service delivery systems and tools; institutionalization and implementation of evidence-based programming approaches; and dissemination and application of findings or evaluation results.

Subproject Objective(s): 1) Implement and evaluate a network approach to enhance RtoP; 2) to reduce the critical time lag between availability and implementation of reproductive health research findings at the pre-service, provider, community, and policy levels; 3) to facilitate scale-up of effective programs, tools, and approaches; 4) to increase partnerships in the field, primarily through memorandums of understanding (MOU) with the champions' home agencies; and 5) to improve local input into FHI's research agenda, strengthening the important link between practice and research.

Description: The process of research utilization aims to bridge the gap between research and practice by ensuring that policy-makers, health practitioners, or other decision-makers are able to access, understand, and implement recommendations stemming from new research findings in a timely and efficient manner. Applying the principles of Everett Rogers' *Diffusion of Innovations Theory*, research utilization literature asserts that access to, understanding, translation, and uptake of research findings can be facilitated by influential local opinion leaders who assume the role of advocates or "change agents." In line with the change agent model, the proposed subproject will build on lessons learned from FHI's experience with the innovative pilot Network of Champions sub-project implemented under the CTR agreement.

For FY 05-06, this subprojects seeks to identify/fund four Champions who will undertake a variety of approaches to research utilization. Potential candidates are expected to have a strong background in reproductive health care, be well-respected by professional colleagues and hold substantial authority and leadership in the field. In keeping with lessons learned from FHI's CTR pilot project experience, champions will be selected to be well placed in key institutions in their respective countries. Also in keeping with pilot project experience, the selection process for champions will include input from Enhanced Country Program staff, USAID Mission staff and in-country staff from MOU partner agencies, as possible.

All Champions will be responsible for promoting utilization of CTR/CRTU research findings and implementation of evidence-based practices. Specific scopes of work will be negotiated with each Champion based on country needs/priorities, agreements reached with their home institutions, and the change opportunities which are within the champion's scope of influence. Each Champion may be

managed differently, as each scope of work requires. However, it is expected that the bulk of their energy will be devoted to advocacy and networking, and that FHI will devise ways to minimize the time and cost associated with administration. Champions will be oriented regarding FHI's Research Utilization efforts and the Enhanced Country Program to equip them with the knowledge and advocacy skills needed to fulfill their roles and responsibilities as champions. Following orientation, each Champion will undertake an iterative process supported by FHI/NC staff to develop a focused strategic plan to increase awareness and utilization of the CRTU reproductive health topics for which they are best positioned to advocate.

Champions will have clearly outlined reporting requirements and deadlines. These include: a work plans and timelines; summaries of meetings or other activities; and written implementation plans, as needed. Champions will provide FHI with bi-monthly progress reports. In turn, FHI will provide scientific and educational materials, technical assistance, and, where appropriate and possible, funds for implementation activities. FHI RtoP and field staff will maintain communication with each Champion via phone, e-mail and other means as appropriate. FHI regional office staff will facilitate the Champions' work by offering logistic support and technical advice. Additional support, technical assistance, and evaluation will be provided through country visits by RtoP and other headquarters-based staff in conjunction with ongoing activities.

A monitoring and evaluation plan for this subproject will be developed and implemented so that progress and achievement of key outputs and outcomes are tracked. Evaluation results will be used to inform plans for continuation of the subproject and will also contribute to the evidence base for improving research utilization using a change agent model.

The Network of Champions will have a special relationship to the Enhanced Country Program:

- At least two champions will be placed as an "advance guard" for the Enhanced Country Program and chosen from countries eligible for EC Program status in the next two years. The two other champions will be established in non-EC Program countries.
- Champions located in ECP target countries will be asked to facilitate FHI's efforts to establish their presence through activities like assisting FHI to identify consultants, or facilitating establishment of relations with the MoH or local organizations/institutions. Steps will be taken to link champions to in-country MOU partner staff to facilitate local dialog and cooperation in achieving the CRTU's objectives. Once FHI's presence is established, the Champion's scope of work will be developed in consultation with the country office to harmonize efforts and avoid overlap.

FY Workplan:

- Four champions will be recruited. MoUs with their home institutions will be negotiated and signed. The Champions will be oriented and equipped to support CRTU objectives.
- Specific scopes of work will be negotiated for each Champion.
- Monitoring and evaluation plan to track Champion contributions to changes in policies and practices will be designed and installed.

Implementing Best Practices Consortium

Status: To be approved **Projected End Date:** September 30, 2006

Country(ies): Worldwide

FCO: 113116 **Technical Monitor:** E McGinn

Collaborating Agency(s): World Health Organization/Reproductive Health and Research Unit; USAID; 20+ partner agencies, including many leading CAs and several CRTU MOU partners (EngenderHealth, Management Sciences for Health, Population Council)

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting subproject, the outcomes addressed by participation in the IBP Consortium and use of its unique knowledge sharing tools cut across the strategies. Broadly they pertain to the following: dissemination of research findings, provision of technical assistance to US-based and in-country partners, and identification and implementation of new models for research utilization.

Subproject Objective(s): To support the IBP Consortium's efforts: 1) to coordinate joint activities, evaluate progress, and build consensus among U.S. and in-country partners: 2) to provide support, sustain commitment, and assess the achievements of the Kenya IBP Country Team in their efforts to reduce maternal mortality in seven selected districts; 3) to share research utilization experiences and lessons learned among audiences in both domestic and international contexts; 4) to identify and document innovative and effective knowledge sharing models; 5) to implement knowledge sharing models to improve reproductive health practices in at least two countries; and 6) to document success stories, challenges, and lessons learned from implementation of regional/country action plans.

At an institutional level, this subproject aims:

- To identify how FHI's institutional goals can dovetail with those of the IBP.
- To incorporate partnerships with the IBP into existing workplans and strategies.
- To increase utilization of the IBP's Electronic Communication System (ECS) among FHI staff and in-country partners.

Description: FHI is a founding member of the Implementing Best Practices (IBP) Initiative, which was established in 1999 by the World Health Organization's Reproductive Health and Research Unit (WHO/RHR). A formal consortium, which is now comprised of over 20 partner agencies, including the USAID, was established in 2001. The primary goal of the IBP is to improve access to and quality of reproductive healthcare through a systematic approach focused on developing and supporting strategies that introduce, adapt, and apply evidence-based practices in reproductive health. Initiatives such as the IBP have the potential to improve reproductive health outcomes by expanding the quality and reach of reproductive health services worldwide.

Under this subproject, FHI will contribute staff time and resources to sustain active membership in the Consortium and to support activities in the IBP program of work. The subproject will primarily contribute to fulfillment of FHI's mandate to ensure that relevant research findings are broadly disseminated and utilized.

By nature, participation in IBP Consortium will involve coordination and collaboration with other member agencies, including USAID, WHO/RHR, and several CA's and international partners.

FY Workplan:

- Staff will participate in two semi-annual strategy meetings (1st Meeting November 2005; 2nd Meeting TBD).
- FHI will host and organize an IBP Panel at APHA in November 2005.
- "Brown bag" presentations on the IBP and ECS will be held for internal US-based and field staff to facilitate knowledge sharing.
- Staff will continue to facilitate, follow-up, and document activities of the Kenya IBP Country Team.

USAID Best Practices Package: Development and M&E

Status: To be approved **Projected End Date:** June 30, 2007

Country(ies): TBD Africa site selected in consultation with implementing partners. Efforts will be made to locate this activity in an enhanced country.

FCO: 133115 **Technical Monitor:** Erin McGinn

Subgrantee: N/A

Collaborating Agency(s): EngenderHealth, Adventist Development and Relief Agency, Population Council

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
As a cross-cutting subproject, the outcomes addressed cut across strategies. Broadly they pertain to:

- Compile and synthesize knowledge regarding best practices in reproductive health
- Support and address utilization
- Advance research utilization through strengthened partnerships with international service delivery agencies.

Subproject Objective(s): 1) To develop strategies and tools developed to enhance timely and convenient delivery of contraceptive methods; 2) to change policies and guidelines changed to reflect new research findings; 3) to facilitate increased acceptance, support for, and uptake of contraceptive methods; 4) to facilitate USAID HPN officers oversight of the design and evaluation of country-level family planning programs; 5) to identify and market in collaboration with USAID, an improved coordination among cooperating agencies (CAs) to promote basic package of best practices for FP/RH programs; and 6) to facilitate increased funding for and implementation of RH best practices at the country level.

Description: Reproductive health research over the past decade has yielded a number of practices, which, if widely incorporated into practice, have the potential to greatly improve the reproductive health and family planning options of individuals worldwide. Practices such as advance provision and Quick Start of oral contraceptives (OCs), for example, can help reduce the medical barriers new clients may face when seeking to begin OC use. Similarly, specially designed screening tools such as the "Pregnancy Checklist" can expand access to high quality family planning services by strengthening the capacity of community-based workers.

Although such practices have been acknowledged as applicable to many family planning and reproductive health programs, most have not been widely implemented. There is a significant need among FP/RH programs to identify locally-relevant practices which can strengthen both quality and accessibility of services.

FHI proposes to participate in a collaborative effort to develop and field test a package approach to promoting RH best practices. This process will be carried out in collaboration with USAID Missions, the Office of Population and Reproductive Health, and other key partners such as EngenderHealth, the Population Council, and The Adventist Relief Agency.

The package will be directed primarily towards:

- Providing in-country partners with a framework for incorporating state-of-the-art models, tools, and strategies into local programs;

- providing USAID Mission Health, Infectious Disease and Nutrition Officers with the orientation they need to help them to design and evaluate effective family planning programs within their country assignments; and
- providing a higher level of standardized guidance regarding best RH practices across USAID-funded CAs.

The Package will be grounded on a select set of evidence-based best practices and determined in consultation with USAID/DC, research and SD partners, and USAID Mission(s) where the Package will be tested.

Under this subproject FHI will work with USAID and partners to:

- Coordinate a systematic process to identify and select best practices for inclusion in USAID package;
- Pprovide technical assistance in developing a methodology for field-testing the USAID Best Practices Package in two to four countries. Test sites will be collaboratively identified but where possible, complement FHI's *Enhanced Country Program*. FHI will rely on partners for implementation of the field testing, including collection of data;
- Develop a set of promotional materials to accompany the package. Again, implementation of the promotional component is not FHI's sole responsibility and will require additional resources and cost-sharing by partners; and
- Develop indicators to be used by the implementing organizations in order to measure the feasibility and effectiveness of the package approach. Evaluation results will then be used to inform plans for future interventions and shared with service delivery organizations.

This subproject responds to an identified USAID need to mainstream a package of key Best Practices into reproductive health programs. USAID is expected to provide addition special initiative funds (approximately $100,000) to support year 1 development work on this project.

FY Workplan:

- One site will be identified where the package can be tested.
- An in-country stakeholder involvement exercise will be completed.
- A needs assessment tool will be developed/adapted and assessment will be completed.
- A package of best practices will be designed to meet the needs of the field site.
- A monitoring and evaluation plan will be designed and supporting materials produced.
- Institutional arrangement with government and service delivery partner(s) to field test the package made.
- Two coordination meeting with USAID and partners will be convened.
- An electronic forum for communication among collaborating partners will be established.

CRTU Knowledge Management

Status: To be approved **Projected End Date:** April 28, 2010

Countries): Worldwide

FCO: 113118 **Technical Monitor:** B Robinson

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved. IR2= Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: To provide the infrastructure that the technical strategies will call on for synthesis of CTRU results, effective dissemination of findings through multiple vehicles and partnerships (especially the INFO Project), and management of controversy related to research initiatives.

Subproject Objective(s): 1) To implement CRTU research dissemination priorities; 2) to develop and implement communications strategies; 3) to maintain core infrastructures to support CRTU dissemination and issues management.

Description: This cross-cutting subproject, CRTU Knowledge Management, maintains crucial scientific synthesis writing and dissemination infrastructures, manages the planning and implementation of routine and cross-cutting research dissemination and communications, ensures transfer of synthesized CRTU results to JHUCCP's INFO Project for broad dissemination, and develops and implements communications strategies for potentially controversial CRTU research. In hand with augmented utilization efforts under specific Research to Practice subprojects, this sub-project promotes access to relevant syntheses of research information among CRTU partners in a position to influence application in service delivery, provider training, and news media, especially in focus countries.

One component of the subproject -- issues management -- has two basic parts: a proactive planning component that helps prevent problems from occurring, and a quick response component that helps mitigate damage once a problem related to USAID-supported contraceptive technology research has come up. In enhanced countries where high-visibility research is conducted, it involves management of partnerships relevant to community outreach, an aspect of research site development.

To facilitate dissemination of accurate information and consistent messages that support research and promote public health, effective knowledge management is crucial. Not all research subprojects can predict the import of their findings, know in advance about environmental factors that may shape interest in those findings, or plan adequately for dissemination of results. By allocating support for cross-cutting and emerging dissemination needs, this subproject maintains the nuts-and-bolts dissemination capacities that the CRTU needs. It gives the CRTU the flexibility for quick action to take advantage of opportunities to collaborate on dissemination for impact. And it ensures close coordination with and transfer of results to the INFO Project and other partners.

FY Workplan:

Implement research dissemination priorities:

- Staff will track progress of programs to identify newsworthy results or accomplishments, summarize these (estimated 20-25 summaries in 05-06) and distribute them to key research stakeholders. Staff will translate relevant summaries into French or Spanish as needed.

- write and distribute 1-2 major syntheses of FHI research and related studies (for example on discontinuation) for use in facilitating discussion among service delivery organizations on needed future research and interventions.
- Staff will repackage and disseminate these 1-2 evidence-based syntheses through various channels to reach colleagues in the developing world, including via the FHI website, distribution to 20+ listservs, reprinting over INFO Project print and electronic vehicles and on CD-ROMs.
- Staff will produce 5-10 handouts on specific topics to support CRTU programs, conferences, workshops, or dissemination to stakeholders, collaborating with CRTU partners wherever possible.

Maintain core infrastructures to support dissemination and issues management:
Staff will:
- Maintain website content and track metrics of Web and KM databases to improve reach of communications.
- Maintain a mailing list of key contacts for targeted information sharing. Update 15% of contacts per year; add new contacts (such as vasectomy experts) to support planned study dissemination.
- Distribute mass and tailored e-mailings (approximately 80/year).
- Conduct print materials distribution, distribution tracking, and storage management.
- Respond to about 6,000 information requests (emails, phone calls, faxes, and postal inquiries) and mail thousands of materials, as freight budget permits.
- Maintain an image database of project-specific photos for use by staff for presentations and publications.
- Coordinate with dissemination staff at CAs and CRTU partners; participate in USAID's HIPNET group for dissemination staff; discuss operationalization of MoUs under CRTU; and participate in ad-hoc inter-agency meetings to promote dissemination of research findings.
- Provide technical assistance to country partners or MoUs for 5-10 small dissemination activities that promote utilization of knowledge management products, e.g., editorial review of documents (such as guidelines), not already budgeted under a specific project FCO.
- Provide direct support to USAID such as writing of at least 3 technical briefs

Issues management:
Staff will:
- Develop and implement two major topical communications strategies on planned topic areas (e.g., FP and HIV; microbicides).
- Coordinate communications approaches among CAs related to issues requiring special media management.
- Develop supporting materials and provide technical assistance to researchers ad hoc topics that come into media focus.
- Support specific Mission requests for assistance.
- Maintain a database documenting media contacts.
- Provide technical assistance to FHI in-house and field office staff regarding media inquiries.

Cross-Cutting
Enhanced Country Programs

Enhanced Country Program Implementation

Status: To be approved **Projected End Date:** April 28, 2010

Country(ies): Worldwide (Kenya, South Africa, 2 TBD Africa, TBD Asia)

FCO: 113117 **Technical Monitor:** T Nutley

Subgrantee: N/A

Collaborating Agency(s): TBD

USAID Intermediate Objective to be addressed: Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded.

Strategy Outcomes(s) to be addressed: The enhanced country program activities will enable FHI to better achieve outcomes under each of the strategy areas.

Subproject Objective(s): 1) To identify and prioritize local reproductive health research and program needs in five focus countries; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs in the focus countries.

Description: The enhanced country program, which will be implemented in five priority countries, will facilitate the public health impact of the CRTU by leading the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the enhanced country program will serve to identify and prioritize local research and program needs, develop and implement country work plans that address those needs, foster collaborative partnerships with local groups, and translate research into practice.

The enhanced country program will be grounded in the following core activities: development and support of field presence through two existing field offices (Kenya and South Africa) and the placement of three additional local staff in existing IMPACT or partner offices in three countries yet to be determined; utilization of research to practice Champions as information gatherers in non-presence countries; engagement of local stakeholders to oversee research-to-practice efforts; country needs assessment and prioritization to inform the development of a research and program agenda that meets needs at the country level; promotion and utilization of USAID Best Practices; program and research project planning and management oversight; monitoring and evaluation of country work plans; management of the overall enhanced country program approach; and mobilization and diversification of resources to sustain and expand enhanced country program implementation.

A steering committee comprised of FHI senior management, and staff from participating divisions will provide technical oversight to all enhanced country program approaches and activities. Within each focus country, activities will be implemented in collaboration with the Ministry of Health, local universities, the USAID Mission, MOU partners, other cooperative agencies as well as local NGOs, research firms, and community/advocacy groups.

FY Workplan:
The enhanced country program will be implemented in a phased approach. During the first year of the CRTU, three of the five focus countries will be selected in collaboration with USAID Missions,

USAID/Washington and the FHI Enhanced Country Program Steering Committee. For the three selected focus countries, the year one work plan will include the following activities:

- The country needs assessment and prioritization methodologies will be developed with technical input from the Steering Committee.
- Contacts and visits will be made with the short listed countries to determine the third focus country.
- In each country, a local stakeholder committee composed of CRTU MOU partners, RH NGOs, CAs, local universities, the MOH and USAID will be formed and regular meetings convened.
- Assessments will be completed in the three focus countries and assessment reports prepared.
- Findings will be presented to the in-country stakeholder committees and stakeholder sub-groups will prioritize findings/local needs.
- Prioritized local needs will be matched with FHI CRTU strategy topics.
- Meetings with in-country partners will be conducted to discuss work plans and identify potential areas for collaboration.
- Annual country work plans will be prepared.
- The development of an M&E plan will be led by the Director for CRTU Evaluation and steering committee members.
- Core support for key staff and enhanced country program management and backstopping will be maintained.

During year one, work will also be conducted to identify the remaining two focus countries (LAC and Asia).

- Discussions with missions in potential focus countries will be conduced; a short list of four possible countries will be generated.
- Site visits will be conducted to select the final four countries.
- A scope of work for the research utilization champions will be developed and champions identified in the focus countries.
- A personnel search will be initiated with the goal of hiring FHI representatives in the two focus countries by early year two.

Evaluation of "What's New and Cool for Youth" Booklet

Status: To be approved

Projected End Date: September 30, 2006

Country(ies): Kenya

FCO: TBD

Technical Monitor: P Ngom

Subgrantee: TBD

Collaborating Agency(s): National Coordinating Agency for Population and Development (NCAPD)

USAID Intermediate Objective to be addressed: IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:

- Increased awareness of issues related to population, reproductive health and HIV/AIDS among in- and out-of-school youth;
- Strengthened evidence base for how best to scale-up distribution of reproductive health tools and materials among in- and out-of-school youth; and
- Increased uptake of appropriate reproductive health services among in- and out-of-school youth.

Subproject Objective(s): To inform NCAPD on how to maximize exposure to this RH booklet to Kenyan youth so as to equip them with knowledge and skills to make informed decisions about their reproductive health needs and rights. More specifically, the proposed subproject will: 1) pilot test targeted interventions aimed at supporting the distribution and utilization of the booklet; 2) gather information on whether the booklet can help improve awareness of RH issues among youth; and 3) identify key opportunities/challenges to inform scale up to other districts.

Description: The National Coordinating Agency for Population and Development (NCAPD), with technical assistance from Family Health International (FHI) and financial support from USAID/Kenya has produced a booklet entitled "What's New and Cool for Youth." The booklet was developed in response to preliminary findings from the 2003 Kenya Demographic and Health Survey (KDHS), which demonstrated a negative shift in the trends of key demographic and health indicators. In Kenya, youth aged 10–24 years comprise 36 percent of the population and each year, a large number of youth enter into their reproductive years. The 2003 KDHS estimated that about 51 percent of Kenyan youth are sexually active, and one third of these engage in high risk sex every year. However, less than 40 percent of parents give their children any information about sex and sexuality. Furthermore, HIV prevalence among youth aged 15-24 years is 8 percent. Given the growing youth population and their vulnerability to health risks associated with unsafe sexual activity, youth in Kenya have a tremendous need for accurate and accessible reproductive health information.

The booklet "What's New and Cool for Youth" aims to reach both in- and out-of-school youth aged 10-24 years with information on various issues such as the relationship between population and development, rights and responsibilities, family planning, HIV/AIDS, and setting short- and long-term goals for various aspects of life including schooling, friendships, and other personal interests. The booklet was launched in August 2005. The proposed subproject aims to field test key interventions aimed at maximizing exposure to the booklet among in- and out-of-school youth and evaluate how these may affect youth's knowledge and attitudes with regard to sexuality, family planning, and HIV/AIDS. Results of the evaluation will inform efforts to scale-up distribution and use of the booklet. Thus, this subproject has the potential to ensure that a substantial portion of the growing youth cohort in Kenya is equipped with the knowledge and skills to make informed decisions about their sexuality, which will in turn lead to improved reproductive health outcomes.

NCAPD is responsible for formulating and overseeing population policies, strategies and programs in Kenya. In 2003, the NCAPD spearheaded the development of the Kenya Adolescent Reproductive Health and Development (ARH&D) policy and the Action Plan to implement it. NCAPD considers "What's New and Cool for Youth" as the first step towards implementing the ARH&D policy. In addition, NCAPD has the mandate to further population activities within the country and, with its district level structure, will ensure maximum reach to the youth.

Findings from this subproject will inform NCAPD on how the booklet has affected knowledge and attitude of in-school youth, and provide evidence for key supporting interventions required for the adequate scaling up of its distribution to a larger number of schools in Kenya as well as out–of–school youth. Since NCAPD has a network of population officers up to the district level, intensifying the dissemination of the booklet to reach more youth is within their mandate.

The booklet has been developed together with other stakeholders from youth serving organizations who may use the booklet as a resource material in their activities. Being one of the stakeholders, the Ministry of Education can recommend that the book be used as a resource.

USAID/Kenya's strong focus on youth programs makes it easy to source for additional resources for enhanced distribution and use of the booklet. In addition, the presence of NGOs that support youth activities can ensure sustainability of this activity.

FY Workplan:

- FHI will work with NCAPD to identify one intervention district to field the sub-project and another one to serve as a comparison district.
- FHI will work with NCAPD to develop orientation tools that will be used to introduce the booklet to in- and out-of-school youth.
- FHI will support NCAPD to conduct training of trainers for NCAPD program officers in the intervention district. The trainers will be exposed to the booklet's orientation tools and trained on how best to impart the content of the booklet to the youth.
- FHI will support NCAPD and its district population officers to roll out the orientation/training to a selected number of teachers, youth-serving organizations and parents of in-school youth. These target groups will be equipped with the necessary skills to enable them impart efficiently the content of the booklet to the youth.
- FHI will carry out monitoring and evaluation of the above activities with the aim of documenting the booklet utilization process and determining whether it has affected awareness of RH issues among youth.

Building Strategic Information Capacity within NASCOP in Kenya

Status: To be approved **Projected End Date:** September 30, 2006

Country(ies): Kenya

FCO: 153102 **Technical Monitor:** P Ngom

Subgrantee: TBD

Collaborating Agency(s): National AIDS and STI Control Programme (NASCOP) and Kenyatta University

USAID Intermediate Objective to be addressed: IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:

- Increased utilization of existing data sources to inform ongoing PEPFAR programming and evidence-based HIV/AIDS interventions.
- Strengthened collaborative relationships between Kenyan institutions and other key local stakeholders for monitoring and evaluation activities.

Subproject Objective(s): To strengthen national systems for strategic information and operations research in order to improve reproductive health, including HIV/AIDS, programming, implementation, monitoring, and evaluation. FHI will work with Kenyatta University's School of Health Sciences and the National AIDS and STI Control Programme (NASCOP) to: 1) Train four students (3 Master's and 1 PhD) in strategic information collation, analysis and interpretation; and 2)Identify key RH/HIV program areas with gaps in strategic information and address these through the students' thesis reports.

Description: According to the most recent population-based estimate of HIV prevalence in Kenya from the country's 2003 Demographic and Health Survey (DHS), 6.7% of Kenyans are living with HIV. In an effort to mitigate the impact of the epidemic in Kenya, the President's Emergency Fund for AIDS Relief (PEPFAR) is continuing to support HIV/AIDS prevention, care and treatment efforts in the country during FY 2005. One key component of the annual PEPFAR Country Operational Plan (COP) for Kenya is continued support for national surveillance and monitoring systems to document outcomes and evaluate the impact of PEPFAR-supported and national HIV/AIDS program activities. To strengthen current monitoring, evaluation and surveillance activities and to promote their sustainability will require strategic capacity building within the Ministry of Health (MOH), especially NASCOP.

The USAID Mission in Kenya has enlisted FHI's technical expertise in monitoring and evaluation and operations research to respond to the identified local need for enhanced monitoring and evaluation capacity at NASCOP and to facilitate effective, efficient and timely exchange of strategic information (SI) among the MOH and other partners in Kenya. FHI's participation and partnership on this subproject was requested by the Mission, rather than proposed by FHI, and PEPFAR funding has been obligated to support FHI's involvement.

This subproject will contribute to increased data utilization for improved HIV/AIDS programming and enhanced capacity of national staff and institutions in Kenya to carry out strategic information activities, including monitoring and evaluation. In collaboration with FHI and the National AIDS and STI Control Programme (NASCOP), Kenyatta University will undertake four targeted evaluations designed to address PEPFAR goals and objectives. The evaluations will be jointly determined in collaboration with Kenyatta University, NASCOP, the USAID strategic information team in Kenya, and local PEPFAR program managers. FHI will provide technical support and mentorship for four graduate students at Kenyatta University, and the thesis research of these students will contribute to the four targeted PEPFAR evaluations. Technical support from FHI will be developed to respond to needs of the selected students,

Kenyatta University, NASCOP's monitoring and evaluation unit, and the Mission's strategic information priorities.

FY Workplan:

- With mentorship and technical guidance from FHI, four masters students at Kenyatta University's School of Health Sciences will be trained in strategic information and write their graduate theses on key programmatic areas identified in collaboration with the Ministry of Health's National AIDS and STI Control Programme (NASCOP).
- FHI will provide technical support to NASCOP and Kenyatta University (KU) to identify key RH program areas where gaps in strategic information currently exist.
- Through collaboration between FHI, NASCOP and KU, those SI gaps that may be addressed through analysis and synthesis of existing data sources will be prioritized for students' theses work.
- In addition to the students theses, a final report entitled "Building strategic information capacity within NASCOP in Kenya through targeted evaluation of PMTCT, VCT, ART and OVC programs" will be prepared.

Kenya Division of Reproductive Health Capacity Development: Follow-on Activity

Status: To be approved **Projected End Date:** July 31, 2007

Country(ies): Kenya

FCO: TBD **Technical Monitor:** C Ruto

Collaborating Agency(s): GTZ, MEASURE Evaluation, Population Council, Engender Health, and the Kenya Ministry of Health – Division of Reproductive Health

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
- Enhanced local capacity for research utilization and evidence-based programming,
- Development of a platform for gathering strategic information and evaluating public health impact,
- Development, testing and implementation of training and supervision approaches; and,
- Incorporation of evidence-based approaches into country-specific guidelines, program documents, and international recommendations.

Subproject Objective(s): 1) To enhance the DRH staff capacity at all levels in research management skills and utilization of data for decision-making to ensure research utilization and evidence-based programming; 2) to provide a clear system and set of guidelines for conducting RH research in Kenya; 3) to provide efficient communications between the DRH (all levels) and partners as facilitated by establishing a DRH web site; and 4) to provide a platform for gathering strategic information and evaluating public health impact through the annotated bibliography on the web site and the existing resource center.

Description: The Kenya Ministry of Health (MOH), Division of Reproductive Health (DRH) has clearly expressed growing concern over the current inability to identify, participate in, and coordinate reproductive health (RH) research conducted in the country which has resulted in duplication, missed opportunities, and disregard for national RH priorities. As a consequence, a systematic pathway for identifying, prioritizing, and utilizing research findings and results in RH programs faces significant obstacles at best. Over the past year, FHI has been assisting the DRH to build its capacity in order to coordinate and make relevant data more readily available to policy makers, program managers, researchers, and individuals. This follow-on activity will build upon the accomplishments of the previous subproject (FCO 3444) by enhancing and scaling-up several ongoing components such as finalizing research management guidelines, roll-out and evaluation of research management and data for decision making trainings, and enhancements to the DRH Web site. All of these activities enhance Kenya's ability to build and improve public health by refining national systems, upgrading skills set, and building infrastructure at the national, provincial, and district level.

The previous subproject has been implemented with collaboration from UNFPA, WHO, DfID, and MEASURE Evaluation. During this funding year, there will be further development and finalizing of the RH research guidelines in partnership with the DRH and other key stakeholders involved in operations research in Kenya. Secondly, the draft RH research management training module developed during the previous funding period will be finalized. Training on data-for-decision-making (using a module developed during the first phase) will be conducted among MOH staff at the district level. In line with the activities conducted during the previous subproject, FHI will continue to assist the DRH to further develop their existing Web site. An evaluation will be conducted to assess the gaps and needs of the Web site. This evaluation will include a DRH web site user's survey that will also serve to inform any improvements

on usage. This subproject will continue to support improvements to the DRH Resource Center including refurbishment and technical assistance for document cataloging and retrieval.

FY Workplan:

RH Research Guidelines activities involve the following:

- Technically revise the draft guidelines with input from other organizations conducting operations research and the DRH.
- Design, produce, print and distribute 500 copies.
- Conduct national launch for distribution of research guidelines and hold additional stakeholders' meeting for orientation as needed. Post the guidelines to the DRH web site.
- Provide technical assistance to DRH staff for initiating, maintaining, and evaluating the new administrative procedures for researchers seeking to collaborate with the DRH.
- Ensure guidelines are included in new National RH policy.

RH Research Management Training Module activities involve the following:

- Continue developing the curriculum from Phase I.
- Revise the curriculum with input from stakeholders and produce a final draft.
- Pilot test the curriculum with DRH staff at the national level (training with 25 participants).
- Finalize the curriculum and produce 300 copies.
- Provide technical assistance to DRH Master Trainers in scale-up of training at the provincial and district level (anticipated participants trained: 200).

Data for Decision Making Training/Module activities include the following:

- Revise and finalize the training curriculum with RH indicators developed by the DRH and MEASURE.
- Design, produce, and print 300 copies of the training module to be used in scale-up of training.
- Provide technical assistance to DRH Master Trainers in scale-up of training at the provincial and district level (anticipated participants trained: 200).

DRH Web site activities include the following:

- Continue developing the DRH Web site with feedback received in Phase I.
- Update the searchable RH research database on the Web site with new material identified in Phase I.
- Conduct user's orientation workshops at the national and provincial level for DRH staff and other users.
- Track Web site usage and conduct a user's survey to identify additional improvements.
- Finalize all Web site administration documentation.
- Train three DRH staff in administering the DRH Web site and conduct a complete handover to the DRH.

DRH Resource Center activities include the following:

- Collaborate with GTZ to strengthen the DRH Resource Center regarding physical infrastructure, supplies, and systems for users.
- Train three DRH resource center staff in CD-ISIS cataloguing software and administering updates to the RH research annotated bibliography and web-based database.
- Provide technical assistance to DRH Resource Center staff to ensure that new research is being captured and added to the RH database developed in Phase I.

Cross-Cutting
Technical Leadership/Research Synthesis

Research Ethics Training Curriculum for Community Representatives (RETC-CR)

Status: Ongoing **Projected End Date:** December 31, 2006

Country(ies): Worldwide

FCO: 172000 **Technical Monitor:** S Tenorio

Strategy Outcomes to be addressed:

- As a cross-cutting subproject, this activity is related to all the strategies. It supports indirectly those outcomes relating to capacity building and quality research

Subproject Objective(s): To provide basic education to community representatives about their roles and responsibilities in the research process and empower them to provide appropriate input on ethical issues at every level of the research process. Community representation optimizes the protection of research participants, enhances investigator's perception of the research goals, improves the way research is designed, and ensures that research is responsive to community culture, needs and expectations.

Description: The need to involve the communities where research projects are going to be conducted in the planning, design, implementation and dissemination of the research is being increasingly recognized. A new educational tool, The Research Ethics Training Curriculum for Community Representatives (RETC-CR), was recently developed by The Office of International Research Ethics (OIRE) in collaboration with Field Information and Training Services, HIV Prevention Trials Network and the Behavioral and Social Sciences Research Group. The curriculum was developed with the support of The Andrew W. Mellon Foundation and the National Institute of Child Health and Human Development (NICHD). The RETC-CR was designed to provide basic training on research ethics to community representatives, to empower them to actively participate throughout the research process. It may be used either as an interactive self-study program or a participatory group training experience. The RETC-CR has been globally disseminated. The English version of the curriculum is currently available in print, CD-ROM and on the web.

Also, with support from the NICHD, translations of the RETC-CR into French, Portuguese and Spanish have been recently completed. The French and Spanish translations are already available on the web.

The following activities will be undertaken in this subproject:

- The online version of the RETC-CR Portuguese translation will be developed.
- 2,000 CD-ROMs, which will include English, French, Portuguese and Spanish versions of the RETC-CR will be produced.
- 500 print version copies of the RETC-CR translation (French, Portuguese and Spanish) will be produced.
- A RETC-CR Instructor's Guide for Training-of-Trainers will be developed. The purpose of this guide is to provide guidance to trainers to plan and conduct training workshops based on the RETC-CR.
- 200 printed copies of the English version of the RETC-CR Instructor Guide for Training-of-Trainers will be produced.
- If funds are available, the RETC-CR will be translated to another language and made web available. The language will be selected based on identified need and/or programmatic importance.

This subproject is a continuation of work supported under the CTR (see FCO 2710) and with Mellon Foundation funding.

FY Workplan:

- Staff will post the Portuguese translation on the web.
- Staff will produce 2,000 copies of the 4-language CD-ROM and 500 print copies each of the French, Portuguese and Spanish translations for dissemination.
- Staff will complete and produce the RETC-CR Instructor's Guide.

BASS Technical Leadership

Status: To be approved **Projected End Date:** April 28, 2010

Country(s): Worldwide

FCO: 116103 **Technical Monitor:** L Severy

USAID Intermediate Results to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR2= Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
- Proposals developed to further our research on hormonal methods, barrier methods, LAPMs and integration of family planning into HIV services.
- Papers prepared that report on findings from the CTR with an emphasis on results that lead to an increase in under-used methods and to the integration of FP services into HIV programs.

Subproject Objective(s): 1) To develop behavioral and social science projects to be funded under the CRTU; and 2) to prepare papers that report on findings of research funded under the CTR.

Description: FHI strategies under the new CRTU emphasize increasing the acceptance and continued use of existing methods of contraception and of integrating FP into HIV services. BASS's research activities are designed to enhance the likelihood of successful trials and interventions by attending to concepts such as formative research, community preparedness, ethics and informed consent, and acceptability – all within cultural contexts. As a result, this research should lead to greater acceptance and higher continuation rates of methods and thus to important public health outcomes.

This subproject funds the time that various members of BASS spend in preparing concept papers in these areas. Once approval has been received to proceed with a concept paper, an FCO will be assigned.

The subproject also funds the preparation of papers for which the research was funded under the CTR. Various staff members in BASS will take findings from analysis and reports and turn them into papers.

FY Workplan:
- Final reports will be completed and papers/manuscripts written for CTR related subprojects.
    - Nancy Williamson and Kerry McLoughlin will write papers emanating from the Kenyan and Ugandan subprojects focusing upon those couples successfully demonstrating continued use of condoms.
    - Natasha Mack will write papers emanating from the Mexican subproject focusing on young MSM.
    - Greg Guest and Larry Severy will write papers focusing upon measurement and validity issues related to self report data.
    - Betsy Tolley and Larry Severy will write papers emanating from the couple acceptability research conducted in Pune, India.
- Concept proposals will be prepared.
- Staff will respond to USAID consultations on various issues.

BIOS Technical Leadership

Status: To be approved **Projected End Date:** April 28, 2010

Country(s): Worldwide

FCO: 119100 **Technical Monitor:** R. Dominik

USAID Intermediate Results to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR2= Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
- To bring to market safe and effective contraceptives.
- To increase access, improve quality and expand use of contraceptives.

Subproject Objective(s): 1) To help develop health services, clinical and behavioral research subprojects to be funded under the CRTU; and 2) to provide statistical expertise needed for the continued development, distribution and evaluation of safe and effective contraceptive products and services.

Description: This subproject funds the time that various members of BIOS spend in preparing concept papers in collaboration with HSR, BASS and CRD staff for new CRTU subprojects. Once approval has been received to proceed with a concept paper, an FCO will be assigned.

The subproject also funds: 1) the contribution of BIOS staff to interagency committees and other decision making groups involved in the development and evaluation of contraceptive products and services of interest to USAID; and 2) the development and review of statistical methods needed to accelerate or improve the quality of contraceptive research carried out under the CRTU.

FY Workplan:
- BIOS will collaborate with CRD, BASS and HSR staff in the development of new research proposals under the CRTU.
- BIOS will participate in working groups, FDA meetings and other inter-organizational meetings defining clinical research standards for contraceptive device and drug development.
- BIOS will respond to USAID consultations on various issues.
- BIOS will prepare expert reviews of statistical methods for contraceptive development and family planning research which may be submitted for publication.

CRD Technical Leadership

Status: To be approved **Projected End Date:** April 10, 2010

Country(s): Worldwide

FCO: TBD **Tech Monitor:** L Dorflinger

USAID Intermediate Results to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR2= Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
- To bring to market safe and effective contraceptives.
- To increase access, improve quality and expand use of contraceptives.
- To improve uptake and use, as well as continuation of, contraceptives.

Subproject Objective(s): 1) To develop clinical research subprojects to be funded under the CRTU; 2) to support time of key staff to provide technical leadership to partners and organizations, including participation in relevant meetings; and 3) to prepare papers that report on additional findings of clinical research activities funded under the CTR.

Description: This sub-project funds the time that various members of CRD spend in developing ideas and preparing concept papers in strategic areas of the CRTU, including collaborations with HSR, BASS, FITS and BIOS staff. Once approval has been received to proceed with a concept, an FCO will be assigned for further work. The sub-project also funds the contribution of CRD staff to interagency committees and other decision making groups involved in the development and evaluation of contraceptive products and services of interest to USAID. Finally, a number of key research activities were completed under the CTR for which additional analyses, papers and Research to Practice documents were anticipated but not completed because of time. These will be funded under this FCO.

FY Workplan:
- CRD will collaborate with BASS, HSR, FITS and BIOS staff in the development of new concept and research proposals under the CRTU.
- CRD staff will write papers/manuscripts for CTR related subprojects. Examples include:
    - additional analyses and papers from the Madagascar female condom research study conducted by HSR;
    - additional analyses from the condom choice studies in Jamaica, Ghana, Kenya and South Africa;
    - an analysis of pregnancy rates of hormonal contraceptive methods in developing countries using the hormonal contraception and HIV acquisition study database .
- CRD staff will respond to USAID consultations on various issues.
- As appropriate, CRD staff will participate in working groups, FDA meetings and other inter-organizational meetings defining clinical research standards for contraceptive device and drug development.
- As appropriate, CRD technical leaders will review reports and potential publications at the request of journals or reproductive health colleagues in order to advance the goals of the CRTU.

Technical Leadership for WHO Family Planning Guidelines

Old Title: Development of Guidelines on Contraceptive Use: "CIRE System"

Status: To be approved

Projected End Date: June 30, 2007
(FHI will assess the need to renew at this point)

Country(s): Worldwide

FCO: TBD

Tech Monitor: K. Nanda

Collaborating Agency(s): WHO, JHU, CDC

USAID Intermediate Objective to be addressed:
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: To increase the use of evidence-based practices in reproductive health service delivery programs in developing countries.

Subproject Objective(s): 1) Compile and synthesize knowledge regarding best practices in reproductive health; 2) advance research utilization through strengthened partnerships with international service delivery agencies ; and 3) implement strategic research dissemination activities to support utilization goals.

Description: The World Health Organization (WHO) provides evidence-based family planning guidance for use worldwide. WHO currently has two such guidelines, *Medical Eligibility Criteria for Contraceptive Use* and *Selected Practice Recommendations for Contraceptive Use*, which are widely used globally and often incorporated into national family planning standards and guidelines. A third guideline, the *Handbook for Providers*, is currently in development.

To ensure that these guidelines remain up-to-date, WHO, in collaboration with CDC and the INFO Project at JHU, developed the Continuous Identification of Research Evidence (CIRE) system to identify, synthesize, and evaluate new scientific evidence as it becomes available. The second component of the system, conducted by CDC and WHO, and assisted by FHI, consists of:

1) determining which new research reports are relevant;
2) critically appraising new, relevant reports;
3) preparing or updating systematic reviews;
4) obtaining peer review of systematic reviews and revising as appropriate; and
5) providing final systematic reviews to WHO Secretariat.

FHI staff also are involved in: writing several chapters of the *Handbook for Providers*; serve as peer-reviewers on an ongoing basis for reviews generated from the CIRE system; and providing technical leadership by participating in WHO Expert Working Group meetings and other assistance to WHO secretariat as needed. This leadership role also involves identifying research gaps identified by the systematic reviews and Expert meetings, and working with WHO to fill these research needs.

FY Workplan:

- FHI staff will draft 2 systematic reviews and present them at the next WHO MEC meeting in 2006.
- FHI staff will draft 2 systematic reviews for presentation at next WHO SPR meeting in 2007.
- FHI staff will update 3 systematic reviews from the previous MEC/SPR and submit manuscripts for publication.
- FHI staff will serve as peer-reviewers on an ongoing basis for new and updated reviews (anticipated 2-4) generated from the CIRE system.
- FHI staff will participate in the proposed Expert Working Group meetings for the MEC in Geneva in 2006.

- FHI staff will provide continuing review, editing and writing for several chapters in the Global Handbook on Contraceptive Technology as requested by WHO and JHU-CCP.
- FHI will work with WHO on a Male Condom Fact sheet.
- FHI staff will provide technical leadership for developing research projects to meet research gaps identified by the systematic reviews or Expert meetings.
- FHI staff will print 2,000 copies of the quick guide to the MEC in English, French and Spanish, publish these on the web and promote them to CAs and in-country.
- FHI staff will assist field offices by reviewing hand-outs or Powerpoint presentations of the introduction to MEC and SPR workshops in Kenya and Uganda to ensure field offices are presenting the information accurately.
- FHI staff will provide continued technical assistance to the WHO Secretariat as requested for additional related activities.
- It is anticipated that the updated MEC and SPR will be incorporated into family planning guidelines worldwide.
- It is anticipated that the *Handbook for Providers* will replace *Essentials of Contraceptive Technology* and all the other current handbooks in use globally by family planning providers.

Cochrane Fertility Review Group

Status: To be approved **Projected End Date:** April 28, 2010

Country(s): Worldwide

FCO: 112112 **Technical Monitor:** D. Grimes

Subgrantee: N/A

Collaborating Agency(s): N/A

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR2= Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: To perform systematic reviews and meta-analyses of randomized controlled trials on methods of family planning. The Cochrane Collaboration is widely recognized as the most important source of high-quality evidence about the safety and effectiveness of fertility regulation methods. FHI will continue its international leadership in this effort.

Subproject Objective(s): Cochrane reviews identify all the relevant randomized controlled trials in specific areas of interest, synthesize the results, and publish the conclusions in the Cochrane Library and in secondary articles in the scientific literature. We continue to seek domestic and international collaborators for reviews. Through this process, we hope to spread the technique of systematic reviews of evidence worldwide.

Description: This is a continuing subproject. The Cochrane Collaboration produces the highest quality scientific evidence on family planning topics for clinicians, public health workers, and policymakers.

A dangerous lag of over a decade exists between publication of life-saving research and its introduction into medical practice. Much of this utilization gap relates to the challenges in finding and absorbing the best available evidence about clinical practice. The Fertility Regulation Review Group, based in Leiden, the Netherlands, coordinates a worldwide effort to identify, analyze, and disseminate in easily understood fashion the scientific evidence on family planning.

The Cochrane systematic review process has five discrete steps: title registration with the central office in Leiden; submission of a protocol, which is a formal description of the methods to be used in searching and synthesizing the literature; peer-review and subsequent approval of the protocol; conduct the actual review and report writing using Cochrane software; and peer-review of the submitted review before its final acceptance for publication in the Cochrane Library. Cochrane reviews are also published in peer-reviewed journals.

FHI is the world leader in producing Cochrane reviews in fertility regulation. Recent reviews at FHI have involved collaborators from many countries around the world. Cochrane reviews have led to important changes in clinical practice, such as stopping the practice of prophylactic antibiotics at IUD insertion, expanding immediate post-abortal and post-partum IUD insertion, and encouraging continuous instead of cyclic use of combined oral contraceptives.

FY Workplan:
The following reviews will be completed and published in the Cochrane Library:

- Gallo M, Nanda K, Grimes DA, Schulz KF. 20 mcg versus >20 mcg Estrogen combined oral contraceptives for contraception.
- Gallo MF, Grimes DA, Schulz KF, d'Arcangues C, Lopez LM. Combination injectable contraceptives for contraception.
- Grimes DA, Lopez LM, Raymond EG, Halpern V, Nanda K, Schulz KF. Spermicide used alone for contraception.
- Halpern V, Grimes DA, Lopez LM, Gallo M. Strategies to improve compliance and acceptability of hormonal methods of contraception.
- Edelman AB, Gallo MF, Jensen JT, Nichols MD, Schulz KF, Grimes DA. Continuous or extended cycle vs. cyclic use of combined oral contraceptives for contraception.
- Cook LA, Pun A, van Vliet H, Gallo MF. Scalpel versus nonscalpel incision for vasectomy.

The following protocols will be published in the Cochrane Library and reviews developed:

- Polis C, Blanchard K, Glasier A, Grimes DA, Harper C, Schaffer K, Trussell J. Advance provision of emergency contraception for pregnancy prevention.
- Grimes DA, et al. Non-steroidal anti-inflammatory drugs for heavy bleeding related to intrauterine devices.

New review topics:

- Two new titles for Cochrane reviews will be registered and protocols developed.

Papers will be revised and published in peer-reviewed journals:

- Lopez LM, Grimes DA, Schulz KF. Non-hormonal drugs for contraception in men: A systematic review. Obstetrics & Gynecology Survey.
- Grimes DA, Gallo MF, Grigorieva V, Nanda K, Schulz KF. Fertility awareness-based methods for contraception. Contraception.

Handsearching:

- Issues of Contraception will be hand-searched for submission to the Cochrane Central Register of Controlled Trials (March 2002 to August 2005).

The following Cochrane reviews will be updated:

- Kuyoh MA, Toroitich-Ruto C, Grimes DA, Schulz KF, Gallo M, Lopez LM. Sponge versus diaphragm for contraception.
- Gallo MF, Lopez LM, Grimes DA, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight.
- Gallo MF, Grimes DA, Lopez LM, Schulz KF. Nonlatex versus latex male condoms for contraception.
- Truitt ST, Fraser AB, Grimes DA, Gallo MF, Schulz KF. Combined hormonal versus nonhormonal progestin-only contraception in lactation.
- Other existing reviews will continue to be updated on a two-year cycle.

HSR Technical Leadership

Status: To be approved **Projected End Date:** April 28, 2010

Country(s): Worldwide

FCO: 114106 **Technical Monitor:** B Janowitz

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR2= Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed:
- Proposals developed to further our research on hormonal methods, barrier methods, LAPMs and integration of family planning into HIV services.
- Papers prepared that report on findings from the CTR with an emphasis on results that lead to an increase in under-used methods and to the integration of FP services into HIV programs.

Subproject Objective(s): 1) To develop health services research subprojects to be funded under the CRTU; and 2) to prepare papers that report on findings of health services research funded under the CRR.

Description: FHI strategies under the new CRTU emphasize increasing the acceptance and continued use of existing methods of contraception and of integrating FP into HIV services. HSR's research aims to find ways of increasing access, quality and efficiency of service provision to accomplish these goals. As a result, our research should lead to greater acceptance and higher continuation rates of methods and thus to important public health outcomes.

This sub-project funds the time that various members of HSR spend in preparing concept papers in these areas. Once approval has been received to proceed with a concept paper, an FCO will be assigned.

The sub-project also funds the preparation of papers for which the research was funded under the CTR. Various staff members in HSR will take findings from analysis and reports and turn them into papers. A list of proposed papers is available.

FY Workplan:
- Staff will complete final reports and write papers/manuscripts for CTR related subprojects.
    - Karen Katz will write a paper on the reproductive health needs of adolescent OVC in Kenya.
    - Donna McCarraher will write a paper on the pregnancy desires and unmet need for family planning among home-based care clients drawing on work in Kenya and South Africa.
    - Dawn Chin-Quee will write papers on comparing the comprehensibility of missed pill instructions and evidence-based pill provision.
    - Joy Baumgartner will write a client focused paper and a provider focused paper and a poster for RHRU priorities conference for the late DMPA clients subproject.
    - Heidi Reynolds will develop a manuscript on results of OR of integration of FP into VCT in Kenya and will revise three developed manuscripts, one on FP vs. PMTCT module, a manuscript related to supervision evaluation and one on providers' perspectives of quality of care. Aaron Beaston-Blaakman will work with Heidi to complete the RH/VCT costing work in Kenya.
    - Jennifer Wesson will complete a manuscript for the IUD checklist subproject and the provider-based educational outreach to stimulate IUD use in Kenya.

    - Sarah Thomsen will complete a manuscript for the Tanzania male and female condom study, and three from the Mombasa CSW peer education/female condom study.
- Concept proposals will be prepared.
- Staff will respond to USAID consultations on various issues.

Cross-Cutting
Product Quality and Compliance

Inter-Laboratory Trials

Status: Ongoing **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 118104 **Technical Monitor:** E Carter

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To conduct annual proficiency trials among accredited independent laboratories and condom manufacturers. This exercise helps ensure PQC's testing competence, and compliance with international laboratory performance standards.

Description: Inter-laboratory trials are key to establishing consistency and comparability among laboratories. Most, if not all, international procurement agencies depend on third-party laboratory testing to determine the acceptance of condoms prior to shipment. USAID and other procurement agencies use the results of these inter-laboratory trials to identify qualified laboratories. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8015).

FY Workplan:

- The annual inter-laboratory trial will be initiated in October 2005. Results and findings from the study will be disseminated in December 2005 to USAID/CSL and all participating laboratories.

International Standards Development

Status: Ongoing **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 118100 **Technical Monitor:** E Carter

Strategy Outcomes(s) to be addressed: An ISO standard for synthetic male condoms and female condoms established.

Subproject Objective(s) To actively participate in international standards organizations to establish new and/or revise existing performance standards for medical devices, pharmaceuticals, and other commodities procured and distributed by USAID.

Description: Product performance standards are required by regulatory agencies to ensure proper and consistent manufacturing and to protect consumers from harm. These internationally recognized consensus standards are used by USAID and other donor organizations when procuring products for developing country use. PQC will contribute its expertise and represent USAID's interests in the standards' community. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8010).

FY Workplan:
Staff will participate in the following meetings:

- September 1-10, 2005: ISO TC 157 Meeting (Berlin, Germany). Agenda items include: Male and Female Condoms, IUDs, and Diaphragms.
- December 6-8, 2005: ASTM Meeting (Dallas, TX).
- September 26-30, 2005: Female Condom Meeting (Baltimore, MD).
- Ad Hoc Meetings as requested by USAID/CSL.

Technical Assistance to Field Programs

Status: Ongoing **Projected End Date:** April 28. 2010

Country(ies): Worldwide

FCO: 118102 **Technical Monitor:** E Carter

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To provide technical assistance to field funded programs and support field services initiatives through training and mentorship.

Description: Existing and potential contraceptive users must be assured that the products they receive are of good quality and will function as expected. Frequent use failure may discourage their acceptance and can jeopardize the sustainability of field programs. This subproject helps to ensure that the integrity of USAID-provided contraceptives and other commodities are adequately maintained during shipment and in-country storage. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8011).

FY Workplan:

- Staff will respond to field complaints and provide technical assistance as needed or at the request of USAID/CSL. Site visits may be required to expedite resolution of complex situations.

Technical Leadership: Collaboration with Multi/Bi-Lateral Procurement Agencies

Status: Ongoing **Projected End Date:** April 28. 2010

Country(ies): Worldwide

FCO: 118101 **Technical Monitor:** E Carter

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To improve donor procurement practices and develop appropriate product specifications for field programs

Description: USAID fully supports collaborations among donor agencies. PQC routinely provides technical assistance in establishing procurement specifications, pre-qualification of potential suppliers, and handling field complaints. These and other activities will continue as appropriate under the CRTU, which are a continuation of activities conducted under the CTR (FCO 8010).

FY Workplan:

- Staff will attend inter-agency meetings and provide Technical Assistance as needed or as requested by USAID/CSL.

Technical Oversight Committee

Status: Ongoing **Projected End Date:** April 28. 2010

Country(ies): Worldwide

FCO: 118103 **Technical Monitor:** E Carter

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To facilitate annual Technical Oversight Committee meetings to review PQC's program activities and strategies for the CRTU

Description: The Technical Oversight Committee, established in 1995, is comprised of technical experts that monitor and advise PQC's program of work. Meetings are held annually, or as needed, to ensure compliance with CRTU requirements. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8015).

FY Workplan:

- TOC meetings will be scheduled in November 2005 and March/April 2006. Ad Hoc meetings may be required to maintain program objectives or at the request of USAID/CSL.

Test Capability Development and Enhancement

Status: Ongoing **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 118105 **Technical Monitor:** E Carter

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To develop and/or enhance technical knowledge and test capability of products procured by USAID and collaborating agencies.

Description: PQC is in constant demand for technical assistance in addressing procurement and research product issues within FHI and from other CAs and donors. This sub-project will provide staff training, educational materials, and on-site experiences for select staff members. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8015).

FY Workplan:

- Training of staff will be planned as needed to fully support USAID/CSL objectives. Development of internal testing capability for new and/or improved contraceptives will be directed by USAID/CSL.

Production Surveillance – Domestic Procurement – OCs, IUDs, Injectables, etc.

Status: Ongoing **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 148102 **Technical Monitor:** S Hamel

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To ensure pre-distribution quality of OCs, IUDs, Injectables, and other non-barrier contraceptives procured domestically by USAID for developing country programs.

Description: USAID distributes a wide range of contraceptives, including IUDs, OCs, implants, and injectables. To verify contractor compliance and to ensure product acceptance, FHI monitors the production and distribution of these commodities. Periodic audits of domestic contract manufacturers are conducted and representative production lots are selected for evaluation prior to distribution to field programs. Pre-qualification audits are performed of potential new suppliers. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8017).

FY Workplan:

- Monitoring of production activities will be performed as scheduled or as needed to meet USAID/CSL procurement objectives. Production lots will be routinely evaluated for acceptance prior to distribution.
- Results of audits and failure investigations, including recommendations for improvement, will be submitted to USAID/CSL.

Production Surveillance – Offshore Procurement – OCs, IUDs, Injectables, etc.

Status: Ongoing **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 148103 **Technical Monitor:** E Carter

Strategy Outcomes(s) to be addressed: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs.

Subproject Objective(s): To ensure pre-distribution quality of OCs, IUDs, Injectables, and other non-barrier contraceptives procured offshore by USAID for developing country programs.

Description: USAID distributes a wide range of contraceptives, including IUDs, OCs, implants, and injectables. To verify contractor compliance and to ensure product acceptance, FHI monitors the production and distribution of these commodities. Periodic audits of offshore contract manufacturers are conducted and representative production batches are selected for evaluation prior to distribution to field programs. Pre-qualification audits are performed on potential new suppliers. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8017).

FY Workplan:

- Potential suppliers will be pre-qualified prior to contract award.
- Monitoring of contract suppliers will be performed as scheduled or as needed to meet USAID/CSL procurement objectives.
- Production lots will be routinely evaluated for acceptance prior to distribution; and results of audits and failure investigations, including recommendations for improvement, will be submitted to USAID/CSL.

Cross-Cutting
Monitoring & Evaluation

Monitoring and Evaluation of the CRTU Program

Old Title: CRTU Monitoring & Evaluation

Status: Ongoing **Projected End Date:** April 28, 2010

Country(ies): Worldwide

FCO: 119501 **Technical Monitor:** S McIntyre

USAID Intermediate Objective to be addressed:
IR1= Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR2= Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
IR3= Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: This subproject will assess the extent to which all strategy outcomes are being addressed.

Subproject Objective(s): 1) To monitor the progress of the CRTU against stated milestones and subproject objectives; and 2) to conduct in-depth periodic or end-point evaluations to measure the attainment of intended outcomes and to assess the relevance and impact of the overall CRTU program.

Description: Overall monitoring and evaluation of the CRTU Program will be carried out under this subproject. While each CRTU subproject has as assigned manager charged with meeting subproject objectives and completing the subproject on time and within budget, this subproject will oversee the gathering of synthesized information to assess and report out to management and to USAID the progress against CRTU milestones and subproject objectives. Most importantly in terms of monitoring, the progress towards stated CRTU outcome measures will be tracked.

In addition, an evaluation to assess the research-to-practice process will be undertaken. Baseline measurements will be sought for key indicators from enhanced focus countries where FHI anticipates a substantial number of activities. These baseline measurements will include selected indicators already available through national family planning or reproductive health programs, DHS data, or other organizations' reports. For example, access to current family planning and reproductive health guidelines at the start of the award will serve as critical baseline data, allowing FHI to determine whether CRTU activities have had any influence on subsequent revisions or updates to the guidelines by project's end.

During years 4 and 5 of the CRTU Program, country-level data will again be collected on the same indicators reported in the original baseline measurements for the targeted countries. We will compare the year 4 and 5 data to the baseline and across countries to prepare a comprehensive report to USAID in year 5 of "lessons learned" and impact of the CRTU program since inception. This report will include a summation of key output and outcome indicators as of the time of reporting.

FY Workplan:
- Approved CRTU subprojects will be mapped to the outcomes that each seeks to address. In this way, gaps can be identified and the tracking of progress toward meeting the selected strategy outcomes will be facilitated.

- A monitoring and evaluation subcommittee will be attached to the Enhanced Country Steering Committee. This subcommittee will develop a protocol for the baseline assessments to be carried out.
- In the first year, baseline reports will be quickly completed for Kenya and South Africa via a combination of desk review and in-country staff. An additional baseline report will be conducted pending identification of the third enhanced focus county.
- Additional procedures and systems for tracking CRTU's progress will be developed and implemented.
- At least one in-service presentation will be made to introduce staff more thoroughly to USAID's new strategic framework and the CRTU's monitoring and evaluation (M&E) plan.
- Briefs summarizing the lessons learned and impact of the CTR Program will be completed for the CTR/CRTU Meeting to be held in Washington, DC on October 18, 2005.
- The Technical Monitor will continue to participate in the USAID M&E Working Group Steering Committee.
- Annual, semi-annual and ad-hoc reports requested by GH/POP USAID will be prepared.